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LEGISLATIVE HISTORY

Public Law 86-618
S. 2197

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DIGEST OF PUBLIC LAW 86-618

COLOR ADDITIVE AMENDMENTS OF 1960. Amends the Federal Food, Drug, and Cosmetic Act as follows: takes color additives out of the scope of the Food Additives Amendment of 1958; repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of harmless coal-tar colors; enacts new, integrated provisions for the separate listing of suitable color additives, safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above mentioned changes; and contains transitional provisions for commercially established colors.

Includes an anti-cancer clause prohibiting the use of color additives found by the Secretary of Health, Education and Welfare to induce cancer in man or animal.

Provides for the establishment of an ad hoc advisory committee to study and report on the question of whether a color additive is a carcinogen.

Provides that nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by the Meat Inspection Act or the Poultry Products Inspection Act.

INDEX AND SUMMARY OF S. 2197

June 9, 1959	Rep. Harris introduced H. R. 7624 which was referred to the House Interstate and Foreign Commerce Committee. Print of bill as introduced.
June 17, 1959	Sens. Hill and Goldwater introduced S. 2197 which was referred to the Senate Labor and Public Welfare Committee. Print of bill as introduced and remarks of Sen. Hill.
Aug. 18, 1959	Senate committee voted to report (but did not actually report) S. 2197.
Aug. 21, 1959	Senate committee reported S. 2197 with amendments. S. Report No. 795. Print of bill and report.
Aug. 24, 1959	Senate passed S. 2197 as reported.
Aug. 25, 1959	S. 2197 was referred to the House Interstate and Foreign Commerce Committee. Print of bill as referred.
June 12, 1960	House committee voted to report (but did not actually report) H. R. 7624.
June 7, 1960	House committee reported H. R. 7624 with amendments. H. Report No. 1761. Print of bill and report.
June 14, 1960	Rules Committee reported a resolution for the consideration of H. R. 7624. H. Res. 559, H. Report No. 1867. Print of resolution and report.
June 25, 1960	House passed S. 2197 with amendments (inserted language of H. R. 7624). H. R. 7624 indefinitely postponed due to the passage of S. 2197.
June 30, 1960	Senate concurred in House amendments to S. 2197.
July 1, 1960	Senate tabled motion by Sen. Javits to reconsider the vote by which S. 2197 was passed.
July 12, 1960	Approved: Public Law 86-618.

HEARING: House Interstate and Foreign Commerce Committee on H. R. 7624.

UNITED STATES HOUSE OF REPRESENTATIVES H. R. 7624

IN SENATE NOVEMBER 1, 1916

REPORT

OF THE SELECT COMMITTEE ON THE MEXICAN QUESTION,
COMPOSED OF SENATORS CHARLES McNARY, JOHN H. HAY, AND
JAMES H. DUFFY

WASHINGTON: GOVERNMENT PRINTING OFFICE, 1916.

A BILL

TO PROVIDE FOR THE PROSECUTION OF CERTAIN CRIMES
COMMITTED IN THE MEXICAN REPUBLIC

86TH CONGRESS
1ST SESSION

H. R. 7624

IN THE HOUSE OF REPRESENTATIVES

JUNE 9, 1959

Mr. HARRIS introduced the following bill; which was referred to the Committee on Interstate and Foreign Commerce

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Color Additive Amend-
4 ments of 1959."

1 TITLE I—AMENDMENTS TO THE FEDERAL
2 FOOD, DRUG, AND COSMETIC ACT

3 DEFINITIONS

4 SEC. 101. Section 201, as amended, of the Federal
5 Food, Drug, and Cosmetic Act is further amended as follows:

6 (a) Paragraph (s) of such section (defining the term
7 “food additive”) is amended by redesignating clause (3)
8 as clause (4), and by inserting immediately before clause
9 (4), as so redesignated, the following new clause:

10 “(3) a color additive; or”.

11 (b) Paragraph (t) of such section is redesignated and
12 otherwise amended to read as follows:

13 “(u) The term ‘safe’, as used in paragraph (s) of this
14 section and in sections 409 and 706, has reference to the
15 health of man or animal.”

16 (c) There is inserted, immediately after paragraph (s)
17 of such section, the following new paragraph:

18 “(t) (1) The term ‘color additive’ means a material
19 which—

20 “(A) is a dye, pigment, or other substance made by
21 a process of synthesis or similar artifice, or extracted,
22 isolated, or otherwise derived, with or without inter-
23 mediate or final change of identity, from a vegetable,
24 animal, mineral, or other source, and

25 “(B) when added or applied to a food, drug, or

1 cosmetic, or to the human body or any part thereof, is
 2 capable (alone or through reaction with other sub-
 3 stance) of imparting color thereto;

4 except that such term does not include any material which
 5 the Secretary, by regulation, determines is used (or intended
 6 to be used) solely for a purpose or purposes other than
 7 coloring.

8 “(2) The term ‘color’ includes black, white, and inter-
 9 mediate grays.”

10 COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE
 11 ADULTERATED OR MISBRANDED FOODS, DRUGS, OR
 12 COSMETICS

13 Food

14 SEC. 102. (a) (1) Clause (2) (A) of section 402 (a),
 15 as amended, of such Act (relating to food deemed adulter-
 16 ated by reason of unsafe additives) is further amended by
 17 striking out the matter within the parentheses and inserting
 18 in lieu thereof the following: “other than one which is (i)
 19 a pesticide chemical in or on a raw agricultural commodity;
 20 (ii) a food additive; or (iii) a color additive”.

21 (2) Section 402 (c), as amended, of such Act (relating
 22 to food deemed adulterated by reason of uncertified coal-tar
 23 color) is amended to read as follows:

24 “(c) If it is, or it bears or contains, a color additive
 25 which is unsafe within the meaning of section 706 (a).”

(3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

4 “(1) If it is a color additive, unless its packaging and
5 labeling are in conformity with such packaging and labeling
6 requirements, applicable to such color additive, as may be
7 contained in regulations issued under section 706.”

8 Drugs

9 (b) (1) Clause (4) of section 501 (a) of such Act
10 (relating to drugs deemed adulterated by reason of uncerti-
11 fied coal tar color) is amended to read as follows: “(4) if
12 (A) it is a drug which bears or contains, for purposes of
13 coloring only, a color additive which is unsafe within the
14 meaning of section 706 (a), or (B) it is a color additive the
15 intended use of which in or on drugs is for purposes of color-
16 ing only and is unsafe within the meaning of section
17 706 (a).”

18 (2) Section 502 of such Act (relating to the circum-
19 stances under which drugs are deemed misbranded) is
20 amended by adding at the end thereof the following new
21 paragraph:

22 “(m) If it is a color additive the intended use of which
23 in or on drugs is for the purpose of coloring only, unless

1 its packaging and labeling are in conformity with such pack-
2 aging and labeling requirements, applicable to such color
3 additive, as may be contained in regulations issued under
4 section 706.”

Cosmetics

(c) (1) Section 601 (e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

9 “(e) If it is not a hair dye and it is, or it bears or con-
10 tains, a color additive which is unsafe within the meaning
11 of section 706 (a).”

12 (2) Section 602 of such Act (relating to the circum-
13 stances under which cosmetics shall be deemed to be mis-
14 branded) is amended by adding at the end thereof the fol-
15 lowing new paragraph:

16 “(e) If it is a color additive, unless its packaging and
17 labeling are in conformity with such packaging and labeling
18 requirements, applicable to such color additive, as may be
19 contained in regulations issued under section 706. This par-
20 agraph shall not apply to packages of color additives which,
21 with respect to their use for cosmetics, are marketed and
22 intended for use only in or on hair dyes (as defined in the
23 last sentence of section 601 (a)).”

1 REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR
2 FOODS, DRUGS, AND COSMETICS

3 SEC. 103. (a) Such Act is further amended by—

4 (1) repealing subsection (b) of section 406 and
5 striking out the subsection designation “(a)” after “SEC.
6 406.” in such section;

7 (2) repealing section 504;

8 (3) repealing section 604; and

9 (4) amending section 701 (e) by (A) striking
10 out “406 (a) or (b)” and inserting in lieu thereof
11 “406”; (B) striking out “504, or 604,”; and (C) in-
12 serting the word “or” after “501 (b),”.

13 (b) Section 706 of such Act is amended to read as
14 follows:

15 “LISTING AND CERTIFICATION OF COLOR ADDITIVES
16 FOR FOODS, DRUGS, AND COSMETICS

17 “When Color Additives Deemed Unsafe

18 “SEC. 706. (a) A color additive shall, with respect to
19 any particular use (for which it is being used or intended
20 to be used or is represented as suitable) in or on food or
21 drugs or cosmetics, be deemed unsafe for the purposes of
22 the application of section 402 (c), section 501 (a) (4), or
23 section 601 (e), as the case may be, unless—

24 “(1) (A) there is in effect, and such additive and
25 such use are in conformity with, a regulation issued under

subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

“(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402 (a) if such article is a food, or within the meaning of section 601 (a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601 (a)).

“Listing of Colors

“(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for

1 use in or on cosmetics, if and to the extent that such addi-
2 tives are suitable and safe for any such use when employed
3 in accordance with such regulations.

4 “(2) (A) Such regulations may list any color additive
5 for use generally in or on food, or in or on drugs, or in or on
6 cosmetics, if the Secretary finds that such additive is suitable
7 and may safely be employed for such general use.

8 “(B) If the data before the Secretary do not establish
9 that the additive satisfies the requirements for listing such
10 additive on the applicable list pursuant to subparagraph (A)
11 of this paragraph, or if the proposal is for listing such addi-
12 tive for a more limited use or uses, such regulations may list
13 such additive only for any more limited use or uses for which
14 it is suitable and may safely be employed.

15 “(3) Such regulations shall, to the extent deemed
16 necessary by the Secretary to assure the safety of the use or
17 uses for which a particular color additive is listed, prescribe
18 the conditions under which such additive may be safely
19 employed for such use or uses (including, but not limited to,
20 specifications, hereafter in this section referred to as toler-
21 ance limitations, as to the maximum quantity or quantities
22 which may be used or permitted to remain in or on the
23 article or articles in or on which it is used; specifications
24 as to the manner in which such additive may be added to

1 or used in or on such article or articles; and directions or
2 other labeling or packaging requirements for such additive).

3 “(4) The Secretary shall not list a color additive un-
4 der this section for a proposed use unless the data before
5 him establish—

6 “(A) that such use, under the conditions of use to
7 be specified in the regulations, will be safe;

8 “(B) that practicable methods of analysis exist
9 for determining the quantity of the pure dye and all
10 intermediates and other impurities contained in such
11 color additive; and

12 “(C) that practicable methods exist for determin-
13 ing the identity and quantity (i) of such additive in
14 or on any article of food, drug, or cosmetic, and (ii)
15 of any substance formed in or on such article because of
16 the use of such additive.

17 “(5) (A) In determining, for the purposes of this sec-
18 tion, whether a proposed use of a color additive is safe, the
19 Secretary shall consider, among other relevant factors—

20 “(i) the probable consumption of, or other relevant
21 exposure from, the additive and of any substance formed
22 in or on food, drugs, or cosmetics because of the use of
23 the additive,

1 “(ii) the cumulative effect, if any, of such additive
2 in the diet of man or animals, taking into account the
3 same or any chemically or pharmacologically related sub-
4 stance or substances in such diet; and

5 “(iii) safety factors which, in the opinion of ex-
6 perts qualified by scientific training and experience to
7 evaluate the safety of color additives for the use or uses
8 for which the additive is proposed to be listed, are gen-
9 erally recognized as appropriate for the use of animal
10 experimentation data.

11 “(B) A color additive (i) shall be deemed unsafe, and
12 shall not be listed, for any use which will or may result in
13 ingestion of all or part of such additive, if the additive is found
14 to induce cancer when ingested by man or animal, or if it
15 is found, after tests which are appropriate for the evaluation
16 of the safety of additives for use in food, to induce cancer
17 in man or animal, and (ii) shall be deemed unsafe, and shall
18 not be listed, for any use which will not result in ingestion
19 of any part of such additive if, after tests which are appro-
20 priate for the evaluation of the safety of additives for such
21 use, or after other relevant exposure of man or animal to
22 such additive, it is found to induce cancer in man or animal.

23 “(6) The Secretary shall not list a color additive under
24 this subsection for a proposed use if the data before him
25 show that such proposed use would promote deception of

1 the consumer in violation of this Act or would otherwise
2 result in misbranding or adulteration within the meaning
3 of this Act.

4 “(7) If, in the judgment of the Secretary, a tolerance
5 limitation is required in order to assure that a proposed use
6 of a color additive will be safe, the Secretary—

7 “(A) shall not list the additive for such use if he
8 finds that the data before him do not establish that
9 such additive, if used within a safe tolerance limita-
10 tion, would achieve the intended physical or other
11 technical effect; and

12 “(B) shall not fix such tolerance limitation at a
13 level higher than he finds to be reasonably required
14 to accomplish the intended physical or other technical
15 effect.

16 “(8) If, having regard to the aggregate quantity of
17 color additive likely to be consumed in the diet or to be
18 applied to the human body, the Secretary finds that the
19 data before him fail to show that it would be safe and other-
20 wise permissible to list a color additive (or pharmacolog-
21 ically related color additives) for all the uses proposed there-
22 for and at the levels of concentration proposed, the Secretary
23 shall, in determining for which use or uses such additive
24 (or such related additives) shall be or remain listed, or
25 how the aggregate allowable safe tolerance for such addi-

1 tive or additives shall be allocated by him among the uses
2 under consideration, take into account, among other rele-
3 vant factors (and subject to the paramount criterion of
4 safety), (A) the relative marketability of the articles in-
5 volved as affected by the proposed uses of the color additive
6 (or of such related additives) in or on such articles, and
7 the relative dependence of the industries concerned on such
8 uses; (B) the relative aggregate amounts of such color
9 additive which he estimates would be consumed in the diet
10 or applied to the human body by reason of the various uses
11 and levels of concentration proposed; and (C) the avail-
12 ability, if any, of other color additives suitable and safe for
13 one or more of the uses proposed.

14 "Certification of Colors

15 " (c) The Secretary shall further, by regulation, provide
16 (1) for the certification, with safe diluents or without dilu-
17 ents, of batches of color additives listed pursuant to subsec-
18 tion (b) and conforming to the requirements for such addi-
19 tives established by regulations under such subsection and
20 this subsection, and (2) for exemption from the requirement
21 of certification in the case of any such additive, or any listing
22 or use thereof, for which he finds such requirement not to be
23 necessary in the interest of the protection of the public
24 health.

1 “Procedure for Issuance, Amendment, or Repeal of Regula-
2 tions

3 “(d) The provisions of section 701 (e), (f), and (g)
4 of this Act shall apply to and in all respects govern pro-
5 ceedings for the issuance, amendment, or repeal of regula-
6 tions under subsections (b), (c), or (e) of this section
7 (including judicial review of the Secretary’s action in such
8 proceedings) and the admissibility of transcripts of the record
9 of such proceedings in other proceedings, except that—

10 “(1) the Secretary’s order after public hearing
11 (acting upon objections filed to an order made prior
12 to hearing) shall be subject to the requirements of sec-
13 tion 409 (f) (2) ; and

14 “(2) the scope of judicial review of such order
15 shall be in accordance with the third sentence of para-
16 graph (2), and with the provisions of paragraph (3),
17 of section 409 (g) .

18 “Fees

19 “(e) The admitting to listing and certification of color
20 additives, in accordance with regulations prescribed under
21 this Act, shall be performed only upon payment of such
22 fees, which shall be specified in such regulations, as may be
23 necessary to provide, maintain, and equip an adequate serv-
24 ices for such purposes.

“Exemptions

2 “(f) The Secretary shall by regulation (issued without
3 regard to subsection (d)) provide for exempting from the
4 requirements of this section any color additive or any spe-
5 cific type of use thereof, and any article of food, drug, or
6 cosmetic bearing or containing such additive, intended solely
7 for investigational use by qualified experts when in his
8 opinion such exemption is consistent with the public health.”

CONFIDENTIALITY OF TRADE SECRETS

SEC. 104. Section 301 (j), as amended, of such Act,
prohibiting disclosure of trade secrets, is amended by strik-
ing out “or 704” and inserting in lieu thereof “704, or 706”.

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

14 SEC. 105. Such Act is further amended by—

(a) striking out, in section 301 (i) thereof (relating to forgery or unauthorized use of certain identification devices), “404, 406 (b), 504, 506, 507, or 604”, and inserting in lieu thereof “404, 506, 507, or 706”;

(b) (1) striking out, in clause (3) of section 303 (c) (relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

24 (c) striking out “harmless coloring” in section
25 402 (d) (relating to nonnutritive substances in con-

fectionery) and inserting in lieu thereof “authorized coloring”.

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

DEFINITIONS

SEC. 201. As used in this title, the term “basic Act” means the Federal Food, Drug, and Cosmetic Act; the term “enactment date” means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

EFFECTIVE DATE

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED COLORS

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional

1 listing) of a color additive under this section for any use
2 shall, unless sooner terminated or expiring under the pro-
3 visions of this section, expire (A) on the closing date (as
4 defined in paragraph (2) of this subsection) or (B) on the
5 effective date of a listing of such additive for such use under
6 section 706 of the basic Act, whichever date first occurs.

7 (2) For the purposes of this section, the term "closing
8 date" means (A) the last day of the two and one-half year
9 period beginning on the enactment date or (B), with respect
10 to a particular provisional listing (or deemed provisional
11 listing) of a color additive or use thereof, such later closing
12 date as the Secretary may from time to time establish pursu-
13 ant to the authority of this paragraph. The Secretary may
14 by regulation, upon application of an interested person or on
15 his own initiative, from time to time postpone the original
16 closing date with respect to a provisional listing (or deemed
17 provisional listing) under this section of a specified color ad-
18 ditive, or of a specified use or uses of such additive, for such
19 period or periods as he finds necessary to carry out the pur-
20 pose of this section, if in the Secretary's judgment such ac-
21 tion is consistent with the objective of carrying to completion
22 in good faith, as soon as reasonably practicable, the scientific
23 investigations necessary for making a determination as to
24 listing such additive, or such specified use or uses thereof,
25 under section 706 of the basic Act. The Secretary may ter-

1 minate a postponement of the closing date at any time if he
2 finds that such postponement should not have been granted,
3 or that by reason of a change in circumstances the basis for
4 such postponement no longer exists, or that there has been
5 a failure to comply with a requirement for submission of
6 progress reports or with other conditions attached to such
7 postponement.

8 (b) Subject to the other provisions of this section—

9 (1) any color additive which, on the day preceding
10 the enactment date, was listed and certifiable for any
11 use or uses under section 406 (b), 504, or 604, or under
12 the third proviso of section 402 (c), of the basic Act,
13 and of which a batch or batches had been certified for
14 such use or uses prior to the enactment date, and

15 (2) any color additive which was commercially
16 used or sold prior to the enactment date for any use or
17 uses in or on any food, drug, or cosmetic, and which
18 either, (A), on the day preceding the enactment date,
19 was not a material within the purview of any of the
20 provisions of the basic Act enumerated in paragraph (1)
21 of this subsection, or (B) is the color additive known as
22 synthetic beta-carotene,

23 shall, beginning on the enactment date, be deemed to be
24 provisionally listed under this section as a color additive for
25 such use or uses.

1 (c) Upon request of any person, the Secretary, by
2 regulations issued under subsection (d), shall without de-
3 lay, if on the basis of the data before him he deems such
4 action consistent with the protection of the public health,
5 provisionally list a material as a color additive for any use
6 for which it was listed, and for which a batch or batches of
7 such material had been certified, under section 406 (b) , 504,
8 or 604 of the basic Act prior to the enactment date, although
9 such color was no longer listed and certifiable for such use
10 under such sections on the day preceding the enactment date.
11 Such provisional listing shall take effect on the date of pub-
12 lication.

13 (d) (1) The Secretary shall, by regulations issued or
14 amended from time to time under this section—

15 (A) insofar as practicable promulgate and keep
16 current a list or lists of the color additives, and of the
17 particular uses thereof, which he finds are deemed pro-
18 visionally listed under subsection (b) , and the presence
19 of a color additive on such a list with respect to a
20 particular use shall, in any proceeding under the basic
21 Act, be conclusive evidence that such provisional listing
22 is in effect;

23 (B) provide for the provisional listing of the color
24 additives and particular uses thereof specified in sub-
25 section (c) ;

1 (C) provide, with respect to particular uses for
2 which color additives are or are deemed to be pro-
3 visionally listed, such temporary tolerance limitations
4 (including such limitations at zero level) and other
5 conditions of use and labeling or packaging require-
6 ments, if any, as in his judgment are necessary to pro-
7 tect the public health pending listing under section 706
8 of the basic Act;

9 (D) provide for the certification of batches of such
10 color additives (with or without diluents) for the uses
11 for which they are so listed or deemed to be listed un-
12 der this section, except that such an additive which is
13 a color additive deemed provisionally listed under sub-
14 section (b) (2) of this section shall be deemed exempt
15 from the requirement of such certification while not sub-
16 ject to a tolerance limitation; and

17 (E) provide for the termination of a provisional
18 listing (or deemed provisional listing) of a color addi-
19 tive or particular use thereof forthwith whenever in his
20 judgment such action is necessary to protect the public
21 health.

22 (2) (A) Regulations under this section shall, from time
23 to time, be issued, amended, or repealed by the Secretary
24 without regard to the requirements of the basic Act, but for
25 the purposes of the application of section 706 (e) of the basic

1 Act (relating to fees) and of determining the availability
2 of appropriations of fees (and of advance deposits to cover
3 fees) , proceedings, regulations, and certifications under this
4 section shall be deemed to be proceedings, regulations, and
5 certifications under such section 706.

6 (B) On and after the enactment date, regulations, pro-
7 visional listings, and certifications (or exemptions from cer-
8 tification) in effect under this section shall, for the purpose
9 of determining whether an article is adulterated or mis-
10 branded within the meaning of the basic Act by reason of
11 its being, bearing, or containing a color additive, have the
12 same effect as would regulations, listings, and certifications
13 (or exemptions from certification) under section 706 of the
14 basic Act. A regulation, provisional listing or termination
15 thereof, tolerance limitation, or certification or exemption
16 therefrom, under this section shall not be the basis for any
17 presumption or inference in any proceeding under section
18 706 (b) or (c) of the basic Act.

19 (3) For the purpose of enabling the Secretary to carry
20 out his functions under paragraph (1) (A) and (C) with
21 respect to color additives deemed provisionally listed, he
22 shall, as soon as practicable after enactment of this Act,
23 afford by public notice a reasonable opportunity to interested
24 persons to submit data relevant thereto. If the data so sub-
25 mitted or otherwise before him do not, in his judgment, es-

1 establish a reliable basis for including such a color additive
2 or particular use or uses thereof in a list or lists promulgated
3 under paragraph (1) (A), or for determining the prevail-
4 ing level or levels of use thereof prior to the enactment date
5 with a view to prescribing a temporary tolerance or toler-
6 ances for such use or uses under paragraph (1) (C), the
7 Secretary shall establish a temporary tolerance limitation at
8 zero level for such use or uses until such time as he finds
9 that it would not be inconsistent with the protection of the
10 public health to increase or dispense with such temporary
11 tolerance limitation.

12 EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS

13 INSPECTION ACTS

14 SEC. 204. Nothing in this Act shall be construed to ex-
15 empt any meat or meat food product or any person from any
16 requirement imposed by or pursuant to the Meat Inspection
17 Act of March 4, 1907, 34 Stat. 1260, as amended or ex-
18 tended (21 U.S.C. 71 and the following), or the Poultry
19 Products Inspection Act (21 U.S.C. 451 and the following).

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

By Mr. HARRIS

JUNE 9, 1959

Referred to the Committee on Interstate and Foreign
Commerce



S. 2197

AN ACT TO AMEND THE LAWS OF THE STATE

RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE, AND TO REPEAL AN ACT APPROVED MARCH TWENTY-NINE, NINETEEN FORTY-ONE, RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE, AND TO REPEAL AN ACT APPROVED MARCH TWENTY-NINE, NINETEEN FORTY-ONE, RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE.

A BILL

FOR THE PURPOSE OF AMENDING THE LAWS OF THE STATE RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE, AND TO REPEAL AN ACT APPROVED MARCH TWENTY-NINE, NINETEEN FORTY-ONE, RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE, AND TO REPEAL AN ACT APPROVED MARCH TWENTY-NINE, NINETEEN FORTY-ONE, RELATIVE TO THE REGULATION OF THE BUSINESS OF INSURANCE.



86TH CONGRESS
1ST SESSION

S. 2197

IN THE SENATE OF THE UNITED STATES

JUNE 17, 1959

Mr. HILL (for himself and Mr. GOLDWATER) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Color Additive Amend-
4 ments of 1959".

1 TITLE I—AMENDMENTS TO THE FEDERAL FOOD,
2 DRUG, AND COSMETIC ACT

3 DEFINITIONS

4 SEC. 101. Section 201, as amended, of the Federal
5 Food, Drug, and Cosmetic Act is further amended as
6 follows:

7 (a) Paragraph (s) of such section (defining the term
8 “food additive”) is amended by redesignating clause (3) as
9 clause (4), and by inserting immediately before clause (4),
10 as so redesignated, the following new clause:

11 “(3) a color additive; or”.

12 (b) Paragraph (t) of such section is redesignated and
13 otherwise amended to read as follows:

14 “(u) The term ‘safe’, as used in paragraph (s) of this
15 section and in sections 409 and 706, has reference to the
16 health of man or animal.”

17 (c) There is inserted, immediately after paragraph (s)
18 of such section, the following new paragraph:

19 “(t) (1) The term ‘color additive’ means a material
20 which—

21 “(A) is a dye, pigment, or other substance made
22 by a process of synthesis or similar artifice, or extracted,
23 isolated, or otherwise derived, with or without inter-
24 mediate or final change of identity, from a vegetable,
25 animal, mineral, or other source, and

“(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

“(2) The term ‘color’ includes black, white, and intermediate grays.”

COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE
ADULTERATED OR MISBRANDED FOODS, DRUGS, OR COSMETICS

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402 (a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: “other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive”.

(2) Section 402 (c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

1 “(c) If it is, or it bears or contains, a color additive
2 which is unsafe within the meaning of section 706 (a).”

3 (3) Section 403 of such Act (relating to the circum-
4 stances under which food is deemed misbranded) is amended
5 by adding at the end thereof the following new paragraph:

6 “(1) If it is a color additive, unless its packaging and
7 labeling are in conformity with such packaging and labeling
8 requirements, applicable to such color additive, as may be
9 contained in regulations issued under section 706.”

10

Drugs

11 (b) (1) Clause (4) of section 501 (a) of such Act (re-
12 lating to drugs deemed adulterated by reason of uncertified
13 coal-tar color) is amended to read as follows: “(4) if (A)
14 it is a drug which bears or contains, for purposes of color-
15 ing only, a color additive which is unsafe within the mean-
16 ing of section 706 (a), or (B) it is a color additive the
17 intended use of which in or on drugs is for purposes of
18 coloring only and is unsafe within the meaning of section
19 706 (a).”

20 (2) Section 502 of such Act (relating to the circum-
21 stances under which drugs are deemed misbranded) is
22 amended by adding at the end thereof the following new
23 paragraph:

24 “(m) If it is a color additive the intended use of which

1 in or on drugs is for the purpose of coloring only, unless its
2 packaging and labeling are in conformity with such packaging
3 and labeling requirements, applicable to such color additive,
4 as may be contained in regulations issued under section 706.”

Cosmetics

(c) (1) Section 601 (e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

9 “(e) If it is not a hair dye and it is, or it bears or
10 contains, a color additive which is unsafe within the meaning
11 of section 706 (a).”

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

16 “(e) If it is a color additive, unless its packaging and
17 labeling are in conformity with such packaging and labeling
18 requirements, applicable to such color additive, as may be
19 contained in regulations issued under section 706. This
20 paragraph shall not apply to packages of color additives
21 which, with respect to their use for cosmetics, are marketed
22 and intended for use only in or on hair dyes (as defined in
23 the last sentence of section 601 (a)).”

1 REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR
 2 FOODS, DRUGS, AND COSMETICS

3 SEC. 103. (a) Such Act is further amended by—

4 (1) repealing subsection (b) of section 406 and
 5 striking out the subsection designation “(a)” after
 6 “SEC. 406.” in such section;

7 (2) repealing section 504;

8 (3) repealing section 604; and

9 (4) amending section 701 (e) by (A) striking out
 10 “406 (a) or (b)” and inserting in lieu thereof “406”;
 11 (B) striking out “504, or 604,”; and (C) inserting the
 12 word “or” after “501 (b),”.

13 (b) Section 706 of such Act is amended to read as fol-
 14 lows:

15 “LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR
 16 FOODS, DRUGS AND COSMETICS

17 “When Color Additives Deemed Unsafe

18 “SEC. 706. (a) A color additive shall, with respect to
 19 any particular use (for which it is being used or intended
 20 to be used or is represented as suitable) in or on food or
 21 drugs or cosmetics, be deemed unsafe for the purposes of the
 22 application of section 402 (c), section 501 (a) (4), or
 23 section 601 (e), as the case may be, unless—

24 “(1) (A) there is in effect, and such additive and
 25 such use are in conformity with, a regulation issued

under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii), has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

“(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402 (a) if such article is a food, or within the meaning of section 601 (a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601 (a)).

“Listing of Colors

“(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives

1 for use in or on cosmetics, if and to the extent that such
2 additives are suitable and safe for any such use when em-
3 ployed in accordance with such regulations.

4 “(2) (A) Such regulations may list any color additive
5 for use generally in or on food, or in or on drugs, or in or
6 on cosmetics, if the Secretary finds that such additive is
7 suitable and may safely be employed for such general use.

8 “(B) If the data before the Secretary do not establish
9 that the additive satisfies the requirements for listing such
10 additive on the applicable list pursuant to subparagraph
11 (A) of this paragraph, or if the proposal is for listing such
12 additive for a more limited use or uses, such regulations
13 may list such additive only for any more limited use or
14 uses for which it is suitable and may safely be employed.

15 “(3) Such regulations shall, to the extent deemed neces-
16 sary by the Secretary to assure the safety of the use or uses
17 for which a particular color additive is listed, prescribe the
18 conditions under which such additive may be safely em-
19 ployed for such use or uses (including, but not limited to,
20 specifications, hereafter in this section referred to as toler-
21 ance limitations, as to the maximum quantity or quantities
22 which may be used or permitted to remain in or on the article
23 or articles in or on which it is used, specifications as to the
24 manner in which such additive may be added to or used

1 in or on such article or articles; and directions or other label-
2 ing or packaging requirements for such additive).

3 “(4) The Secretary shall not list a color additive under
4 this section for a proposed use unless the data before him
5 established—

6 “(A) that such use, under the conditions of use
7 to be specified in the regulations, will be safe;

8 “(B) that practicable methods of analysis exist for
9 determining the quantity of the pure dye and all inter-
10 mediates and other impurities contained in such color
11 additive; and

12 “(C) that practicable methods exist for determin-
13 ing the identity and quantity (i) of such additive in or
14 on any article of food, drug, or cosmetic, and (ii) of
15 any substance formed in or on such article because of
16 the use of such additive.

17 “(5) (A) In determining, for the purposes of this sec-
18 tion, whether a proposed use of a color additive is safe, the
19 Secretary shall consider, among other relevant factors—

20 “(i) the probable consumption of, or other relevant
21 exposure from, the additive and of any substance formed
22 in or on food, drugs, or cosmetics because of the use of
23 the additive,

24 “(ii) the cumulative effect, if any, of such additive

1 in the diet of man or animals, taking into account the
2 same or any chemically or pharmacologically related
3 substance or substances in such diet; and

4 “(iii) safety factors which, in the opinion of experts
5 qualified by scientific training and experience to evaluate
6 the safety of color additives for the use or uses for which
7 the additive is proposed to be listed, are generally recog-
8 nized as appropriate for the use of animal experimenta-
9 tion data.

10 “(6) The Secretary shall not list a color additive under
11 this subsection for a proposed use if the data before him show
12 that such proposed use would promote deception of the con-
13 sumer in violation of this Act or would otherwise result in
14 misbranding or adulteration within the meaning of this
15 Act.

16 “(7) If, in the judgment of the Secretary, a tolerance
17 limitation is required in order to assure that a proposed use
18 of a color additive will be safe, the Secretary—

19 “(A) shall not list the additive for such use if he
20 finds that the data before him do not establish that such
21 additive, if used within a safe tolerance limitation, would
22 achieve the intended physical or other technical effect;
23 and

24 “(B) shall not fix such tolerance limitation at a
25 level higher than he finds to be reasonably required to

1 accomplish the intended physical or other technical
2 effect.

3 “(8) If, having regard to the aggregate quantity of
4 color additive likely to be consumed in the diet or to be ap-
5 plied to the human body, the Secretary finds that the data
6 before him fail to show that it would be safe and otherwise
7 permissible to list a color additive (or pharmacologically re-
8 lated color additives) for all the uses proposed therefor and
9 at the levels of concentration proposed, the Secretary shall,
10 in determining for which use or uses such additive (or such
11 related additives) shall be or remain listed, or how the
12 aggregate allowable safe tolerance for such additive or addi-
13 tives shall be allocated by him among the uses under con-
14 sideration, take into account, among other relevant factors
15 (and subject to the paramount criterion of safety), (A) the
16 relative marketability of the articles involved as affected by
17 the proposed uses of the color additive (or of such related
18 additives) in or on such articles, and the relative dependence
19 of the industries concerned on such uses; (B) the relative
20 aggregate amounts of such color additive which he estimates
21 would be consumed in the diet or applied to the human body
22 by reason of the various uses and levels of concentration
23 proposed; and (C) the availability, if any, of other color
24 additives suitable and safe for one or more of the uses
25 proposed.

1 “Certification of Colors

2 “(c) The Secretary shall further, by regulation, pro-
3 vide (1) for the certification, with safe diluents or without
4 diluents, of batches of color additives listed pursuant to sub-
5 section (b) and conforming to the requirements for such
6 additives established by regulations under such subsection
7 and this subsection, and (2) for exemption from the require-
8 ment of certification in the case of any such additive, or any
9 listing or use thereof, for which he finds such requirement
10 not to be necessary in the interest of the protection of the
11 public health.

12 “Procedure for Issuance, Amendment, or Repeal of
13 Regulations

14 “(d) The provisions of section 701 (e), (f), and (g)
15 of this Act shall apply to and in all respects govern proceed-
16 ings for the issuance, amendment, or repeal of regulations
17 under subsections (b), (c), or (e) of this section (including
18 judicial review of the Secretary’s action in such proceedings)
19 and the admissibility of transcripts of the record of such pro-
20 ceedings in other proceedings, except that—

21 “(1) the Secretary’s order after public hearing
22 (acting upon objections filed to an order made prior to
23 hearing) shall be subject to the requirements of section
24 409 (f) (2) ; and

1 “(2) the scope of judicial review of such order shall
2 be in accordance with the third sentence of paragraph
3 (2), and with the provisions of paragraph (3), of
4 section 409 (g) .

5 “Fees

6 “(e) The admitting to listing and certification of color
7 additives, in accordance with regulations prescribed under
8 this Act, shall be performed only upon payment of such fees,
9 which shall be specified in such regulations, as may be neces-
10 sary to provide, maintain, and equip an adequate service for
11 such purposes.

12 “Exemptions

13 “(f) The Secretary shall by regulation (issued without
14 regard to subsection (d)) provide for exempting from the
15 requirements of this section any color additive or any specific
16 type of use thereof, and any article of food, drug, or cosmetic
17 bearing or containing such additive, intended solely for in-
18 vestigational use by qualified experts when in his opinion such
19 exemption is consistent with the public health.”

20 CONFIDENTIALITY OF TRADE SECRETS

21 SEC. 104. Section 301 (j) , as amended, of such Act,
22 prohibiting disclosure of trade secrets, is amended by strik-
23 ing out “or 704” and inserting in lieu thereof “704, or 706”.

1 CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

2 SEC. 105. Such Act is further amended by—

3 (a) striking out, in section 301 (i) thereof (relat-
4 ing to forgery or unauthorized use of certain identifica-
5 tion devices, “404, 406 (b), 504, 506, 507, or 604”,
6 and inserting in lieu thereof “404, 506, 507, or 706”;

7 (b) (1) striking out, in clause (3) of section 303

8 (c) (relating to color manufacturer’s guarantee), the
9 word “coal-tar” wherever it appears in such clause,
10 and (2) inserting after the word “color”, wherever it
11 appears in such clause, the word “additive”; and

12 (c) striking out “harmless coloring” in section
13 402 (d) (relating to non-nutritive substances in confec-
14 tionery) and inserting in lieu thereof “authorized col-
15 oring”.

16 TITLE II—EFFECTIVE DATE, TRANSITIONAL
17 PROVISIONS, AND EFFECT ON OTHER LAWS

18 DEFINITIONS

19 SEC. 201. As used in this title, the term “basic Act”
20 means the Federal Food, Drug, and Cosmetic Act; the term
21 “enactment date” means the date of enactment of this Act;
22 and other terms, insofar as also used in the basic Act
23 (whether before or after enactment of this Act) shall have
24 the same meaning as they have, or had when in effect,
25 under the basic Act.

EFFECTIVE DATE

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED
COLORS

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later

1 closing date as the Secretary may from time to time establish
2 pursuant to the authority of this paragraph. The Secretary
3 may by regulation, upon application of an interested person
4 or on his own initiative, from time to time postpone the
5 original closing date with respect to a provisional listing (or
6 deemed provisional listing) under this section of a specified
7 color additive, or of a specified use or uses of such additive,
8 for such period or periods as he finds necessary to carry
9 out the purpose of this section, if in the Secretary's judg-
10 ment such action is consistent with the objective of carry-
11 ing to completion in good faith, as soon as reasonably prac-
12 ticable, the scientific investigations necessary for making
13 a determination as to listing such additive, or such specified
14 use or uses thereof, under section 706 of the basic Act. The
15 Secretary may terminate a postponement of the closing
16 date at any time if he finds that such postponement should
17 not have been granted, or that by reason of a change in
18 circumstances the basis for such postponement no longer
19 exists, or that there has been a failure to comply with a
20 requirement for submission of progress reports or with other
21 conditions attached to such postponement.

22 (b) Subject to the other provisions of this section—

23 (1) any color additive which, on the day preceding
24 the enactment date, was listed and certifiable for any
25 use or uses under section 406 (b) , 504, or 604, or under

1 the third proviso of section 402 (c), of the basic Act,
2 and of which a batch or batches had been certified for
3 such use or uses prior to the enactment date, and

4 (2) any color additive which was commercially
5 used or sold prior to the enactment date for any use or
6 uses in or on any food, drug, or cosmetic, and which
7 either (A) on the day preceding the enactment date
8 was not a material within the purview of any of the pro-
9 visions of the basic Act enumerated in paragraph (1)
10 of this subsection, or (B) is the color additive known
11 as synthetic beta-carotene,

12 shall, beginning on the enactment date, be deemed to be
13 provisionally listed under this section as a color additive for
14 such use or uses.

15 (c) Upon request of any person, the Secretary, by regu-
16 lations issued under subsection (d), shall without delay, if
17 on the basis of the data before him he deems such action con-
18 sistent with the protection of the public health, provisionally
19 list a material as a color additive for any use for which it
20 was listed, and for which a batch or batches of such material
21 had been certified, under section 406 (b), 504, or 604 of
22 the basic Act prior to the enactment date, although such
23 color was no longer listed and certifiable for such use under
24 such sections on the day preceding the enactment date. Such
25 provisional listing shall take effect on the date of publication.

1 (d) (1) The Secretary shall, by regulations issued or
2 amended from time to time under this section—

3 (A) insofar as practicable promulgate and keep
4 current a list or lists of the color additives, and of the
5 particular uses thereof, which he finds are deemed pro-
6 visionally listed under subsection (b), and the presence
7 of a color additive on such a list with respect to a
8 particular use shall, in any proceeding under the basic
9 Act, be conclusive evidence that such provisional listing
10 is in effect;

11 (B) provide for the provisional listing of the color
12 additives and particular uses thereof specified in sub-
13 section (c) ;

14 (C) provide, with respect to particular uses for
15 which color additives are or are deemed to be provision-
16 ally listed, such temporary tolerance limitations (in-
17 cluding such limitations at zero level) and other condi-
18 tions of use and labeling or packaging requirements, if
19 any, as in his judgment are necessary to protect the
20 public health pending listing under section 706 of the
21 basic Act;

22 (D) provide for the certification of batches of such
23 color additives (with or without diluents) for the uses
24 for which they are so listed or deemed to be listed under
25 this section, except that such an additive which is a

1 color additive deemed provisionally listed under sub-
2 section (b) (2) of this section shall be deemed exempt
3 from the requirement of such certification while not sub-
4 ject to a tolerance limitation; and

5 (E) provide for the termination of a provisional
6 listing (or deemed provisional listing) of a color addi-
7 tive or particular use thereof forthwith whenever in his
8 judgment such action is necessary to protect the public
9 health.

10 (2) (A) Regulations under this section shall, from time
11 to time, be issued, amended, or repealed by the Secretary
12 without regard to the requirements of the basic Act, but for
13 the purposes of the application of section 706 (e) of the basic
14 Act (relating to fees) and of determining the availability of
15 appropriations of fees (and of advance deposits to cover
16 fees), proceedings, regulations, and certifications under this
17 section shall be deemed to be proceedings, regulations, and
18 certifications under such section 706.

19 (B) On and after the enactment date, regulations, pro-
20 visional listings, and certifications (or exemptions from cer-
21 tification) in effect under this section shall, for the purpose
22 of determining whether an article is adulterated or mis-
23 branded within the meaning of the basic Act by reason of its
24 being, bearing, or containing a color additive, have the same
25 effect as would regulations, listings, and certifications (or

1 exemptions from certification) under section 706 of the basic
2 Act. A regulation, provisional listing or termination
3 thereof, tolerance limitation, or certification or exemption
4 therefrom, under this section shall not be the basis for any
5 presumption or inference in any proceeding under section
6 706 (b) or (c) of the basic Act.

7 (3) For the purpose of enabling the Secretary to carry
8 out his functions under paragraph (1) (A) and (C) with
9 respect to color additives deemed provisionally listed, he
10 shall, as soon as practicable after enactment of this Act,
11 afford by public notice a reasonable opportunity to interested
12 persons to submit data relevant thereto. If the data so
13 submitted or otherwise before him do not, in his judgment,
14 establish a reliable basis for including such a color additive
15 or particular use or uses thereof in a list or lists promul-
16 gated under paragraph (1) (A), or for determining the
17 prevailing level or levels of use thereof prior to the enact-
18 ment date with a view to prescribing a temporary tolerance
19 or tolerances for such use or uses under paragraph (1) (C),
20 the Secretary shall establish a temporary tolerance limi-
21 tation at zero level for such use or uses until such time as
22 he finds that it would not be inconsistent with the protection
23 of the public health to increase or dispense with such tem-
24 porary tolerance limitation.

EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS

INSPECTION ACTS

SEC. 204. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

By Mr. HULL and Mr. GOLDWATER

JUNE 17, 1959

Read twice and referred to the Committee on Labor
and Public Welfare

ishing industry of the State of Alaska, but also of other States bordering on the Pacific Ocean, since the North Pacific area is the breeding and rearing ground for many of the fish taken off the coasts of Oregon, Washington, and California; and

"Whereas it has been brought to the attention of this legislature by Senator Bob Logan, State senator of the State of Alaska, that the first Legislature of the State of Alaska in Senate Joint Resolution 10 has requested that this problem be met by a treaty between the United States, Canada, Japan, and Russia; and

"Whereas such a treaty could provide the most urgently needed protection to properly conserve these fish resources not only for the United States but also for the other nations involved in the fishing area: Now, therefore, be it

"Resolved by the Senate and Assembly of the State of California (jointly), That the Legislature of the State of California respectfully memorializes the President of the United States to do all in his power to bring about a treaty between the United States, Canada, Japan, and Russia to properly protect the fish resources of the North Pacific Ocean, and the Congress of the United States is respectfully memorialized to take all appropriate action in aid of the successful negotiation of such a treaty; and be it further

"Resolved, That the secretary of the senate be hereby directed to transmit copies of this resolution to the President and Vice President of the United States, to the Speaker of the House of Representatives, and to each Senator and Representative from California in the Congress of the United States, and to the Pacific Marine Fisheries Commission."

A resolution of the Assembly of the Legislature of the State of California; to the Committee on the Judiciary:

"HOUSE RESOLUTION 275

"Resolution relative to antilynching legislation

"Whereas the recent lynching of a prisoner in Mississippi has outraged supporters of law and order in all States of our country; and

"Whereas the incident has demonstrated that the problem of lynch-mob action is still very real; and

"Whereas Federal legislation rendering any participation in lynch-mob action an offense against the United States would make a substantial contribution toward discouraging any such incidents in the future: Now, therefore, be it

"Resolved by the Assembly of the State of California, That this body urges the Congress of the United States to make lynching and participation in lynch-mob action a felony under the laws of the United States; and be it further

"Resolved, That the chief clerk of the assembly is directed to transmit copies of this resolution to the President and Vice President of the United States, the Speaker of the House of Representatives, and to each Member of Congress from California."

A letter in the nature of a petition from the City Council of the City of St. Petersburg, Fla., signed by Jennie Cook, clerk, favoring the enactment of legislation to provide funds for the construction of the West Coast Intracoastal Waterway in the State of Florida; to the Committee on Appropriations.

A resolution adopted by the Department of Alaska, the American Legion, Juneau, Alaska, favoring the enactment of legislation to provide funds to maintain the present work schedule of the Arctic Health Research Center in Anchorage, Alaska; to the Committee on Appropriations.

A resolution adopted by the Town Council of Kenneth City, Fla., favoring the enactment of legislation to provide funds for

the construction of the West Coast Intracoastal Waterway in the State of Florida; to the Committee on Appropriations.

A resolution adopted by the Veterans of World War I of the United States of America, Department of Arkansas, protesting against the enactment of House bills 6432 and 7650, relating to veterans' benefits; to the Committee on Finance.

A resolution adopted by the Veterans of World War I of the United States of America, Department of Arkansas, favoring the enactment of legislation to revise non-service-connected pensions for veterans of World War I; to the Committee on Finance.

The memorial of Joseph Ellnzy Camp, of Redondo Beach, Calif., remonstrating against Communist activities in labor unions, and so forth; to the Committee on Labor and Public Welfare.

The petition of J. J. Jones, of Coolidge, Ariz., praying for the enactment of labor reform legislation; to the Committee on Labor and Public Welfare.

A letter in the nature of a petition from Joseph Ellnzy Camp, of Redondo Beach, Calif., relating to contamination of the underground water tables by the use of sewage water; to the Committee on Public Works.

RESOLUTION OF CHAMBER OF COMMERCE, PLYMOUTH, MASS.

Mr. KENNEDY. Mr. President, I ask unanimous consent to have printed in the RECORD a resolution recently adopted by the Plymouth, Mass., Chamber of Commerce, regarding the need for enlarged programs of research into the causes and cure of cancer and diseases of the heart, blood, and vital organs.

There being no objection, the resolution was ordered to be printed in the RECORD, as follows:

Whereas the health of the people of the United States has a direct effect upon its present and future strength; and

Whereas there is an ever-mounting toll of lives taken by cancer and diseases of the heart, blood, and vital organs; and

Whereas the causes and cures of the aforementioned diseases can only be achieved by an immediate concerted effort in the field of medical research: Be it therefore

Resolved, That the Plymouth Chamber of Commerce does hereby urge the Congress of the United States and the U.S. Department of Health, Education, and Welfare, to institute a crash program, i.e., a stepped-up program of research into the causes and cure of cancer and diseases of the heart, blood, and vital organs.

REPORTS OF COMMITTEES

The following reports of committees were submitted:

By Mr. HILL, from the Committee on Labor and Public Welfare, without amendment:

S. 731. A bill to extend certain traineeship provisions of the Health Amendments Act of 1956 (Rept. No. 400).

By Mr. COTTON, from the Committee on Interstate and Foreign Commerce, with amendments:

S. 2183. A bill granting the consent of Congress to interstate compacts for the development or operation of airport facilities (Rept. No. 401).

BILLS AND JOINT RESOLUTION INTRODUCED

Bills and a joint resolution were introduced, read the first time, and, by unani-

mous consent, the second time, and referred as follows:

By Mr. HAYDEN:

S. 2196. A bill for the relief of Vladislav Fotlich; to the Committee on the Judiciary.

By Mr. HILL (for himself and Mr. GOLDWATER):

S. 2197. A bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used; to the Committee on Labor and Public Welfare.

(See the remarks of Mr. HILL when he introduced the above bill, which appear under a separate heading.)

By Mr. ALLOTT (for himself and Mr. LANGRISH):

S. 2198. A bill to amend the Federal Property and Administrative Service Act of 1949; to the Committee on Government Operations.

(See the remarks of Mr. ALLOTT when he introduced the above bill, which appear under a separate heading.)

By Mr. DOUGLAS:

S. 2199. A bill for the relief of Casimir Charles Ramasauskas; to the Committee on the Judiciary.

By Mr. BARTLETT:

S. 2200. A bill for the relief of the estate of Laurence S. Starns; to the Committee on the Judiciary.

By Mr. BARTLETT (for himself and Mr. GRUENING):

S. 2201. A bill to amend section 601 of title 38, United States Code, with respect to the definition of the term "Veterans' Administration facilities"; to the Committee on Labor and Public Welfare.

By Mr. KEFAUVER:

S. 2202. A bill for the relief of Josefine Lepschi; to the Committee on the Judiciary.

S. 2203. A bill for the relief of John H. Smith; and

S. 2204. A bill to amend title 10, United States Code, to provide for the advancement on the retired list of officers of the Army and Air Force specially commended for performance of duty before January 1, 1947, in actual combat; to the Committee on Armed Services.

By Mr. KENNEDY:

S.J. Res. 110. Joint resolution to enable the United States to participate in the resettlement of certain refugees; to the Committee on the Judiciary.

(See the remarks of Mr. KENNEDY when he introduced the above joint resolution, which appear under a separate heading.)

AMENDMENT OF FEDERAL FOOD, DRUG, AND COSMETIC ACT, RELATING TO USE OF SUITABLE COLOR ADDITIVES

Mr. HILL. Mr. President, on behalf of myself, and the Senator from Arizona [Mr. GOLDWATER], I introduce, for appropriate reference, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions—including maximum tolerances—under which such additives may be safely used. I ask unanimous consent to have printed in the RECORD an explanation of the bill, together with a section-by-section analysis.

The PRESIDENT pro tempore. The bill will be received and appropriately

referred; and, without objection, the explanation and section-by-section analysis will be printed in the RECORD.

The bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, introduced by Mr. HILL (for himself and Mr. GOLDWATER), was received, read twice by its title, and referred to the Committee on Labor and Public Welfare.

The explanation and section-by-section analysis presented by Mr. HILL are as follows:

EXPLANATION OF PRINCIPAL FEATURES AND PURPOSES OF PROPOSED COLOR ADDITIVE AMENDMENTS OF 1959

The letter of transmittal briefly summarizes the general objectives of this legislative proposal, the principal reasons which gave rise to it, and previous amendments to the Federal Food, Drug, and Cosmetic Act which, in the case of food, show congressional endorsement of its key principle, i.e., recognition of the scientific soundness of considering the level and other conditions of use in determining the safety of a color additive. A fuller explanation is, however, necessary to an adequate understanding of the major provisions of the bill and their purposes against the background of existing law. In addition, a section-by-section analysis is enclosed for the benefit of those who desire to become conversant with the details of each provision.

A. PRESENT LAW

Under present law, the treatment of color additives differs radically as between the so-called coal-tar colors and others. (For explanation of the technical difference between so-called coal-tar colors and others, see the discussion under "Major Changes Proposed.")

1. Coal-tar colors: The act requires the Secretary to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, or cosmetics; and a food, drug, or cosmetic (other than a hair dye) is deemed adulterated if it bears or contains a coal-tar color other than from a certified batch (except that in the case of drugs this provision applies only where the coal-tar color is used for coloring purposes only). (See secs. 402(c), 406(b), 501(a)(4), 504, 601(e), 604, and 701 (e) and (f) of the act.) Under these provisions, we are without power to admit a color to listing under tolerance limitations. *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958).

2. Other colors: A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirement in the case of cosmetics or drugs (except as pretesting may be required for a coloring component as an incident to official clearance of a new drug under the new drug provisions of the act).

On the other hand, with respect to their use in food, non-coal-tar coloring materials which are classed as "food additives" under the recent food additives amendment of 1958 (Public Law 85-929) are subject to a requirement of official safety clearance, and to establishment of tolerance limitations and other conditions of safe use where necessary for public health protection, except that colors which were in commercial use before January 1, 1958, are allowed a grace period for compliance; this period will expire not later than March 6, 1961. Such food additive colors, however, are not subject to any re-

quirement of batch certification even if, in our view, this would be desirable for the protection of food processors and housewives using the color.

B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. Uniform criteria of admissibility: It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics (other than hair dyes). This would be accomplished by excepting color additives (as defined in the bill) from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived. The present bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics (Delaney committee) (see H. Rept. No. 2356, and H. Rept. No. 2182, 82d Cong.) and by the hearings culminating in the enactment of the food additives amendment of 1958.

2. Safety-of-use principle: The bill adopts for all colors, and for all color uses covered by it, the basic principle of the food additives amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

3. Comprehensive lists: The bill, however, retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors generally recognized by experts as safe for use. While there may have been justification in the case of the food additives amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the

case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color.

4. Certification and exemption from certification: While providing for certification of batches of listed colors, as existing law does for coal tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. We believe, however, that power to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

5. Effective date and transitional provisions: The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act, that is, title I of the bill, would become effective as soon as the bill is enacted.

However, in order to allow an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The commercially established color additives falling under these transitional provisions are (a) those coal tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill, and (b) those noncoal tar colors, and synthetic beta carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic, except that in the case of a coal tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color

additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

C. NEED FOR THE BILL

The interests of consumer protection and of the food, drug, cosmetic, and color industries combine to make urgent the need for enactment of this bill.

1. Consumer protection:

First. Under present law the Government has to perform extensive research to determine whether the colors now listed and being used are in fact harmless and suitable for use in food, drugs, and cosmetics. This testing may require up to 20 years. The bill would require industry to assume the burden of this testing, and would require the tests to be completed within 2½ years or, in individual cases, such additional testing period as is shown to be required and to be consistent with public-health protection. Further, it would allow the Department to place safe tolerance limitations on the amount of color that may be used and the products on which it may be used during this transition period; the Department has no such authority under present law.

Second. Other important aspects of consumer protection afforded by the bill are (a) that the pretesting requirement would be extended to those noncoal tar colors, especially those used in cosmetics and drugs, to which it does not now apply, and (b) that the requirement of certification of batches of color, where necessary for the protection of the public health, would be extended to all colors.

Third. The use of color in foods, drugs, and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is, in many cases, also in the consumer's interest and affirmatively desired by consumers. This is obviously so not only in the case of cosmetics, many of which are designed and purchased for the very purpose of imparting color, but also in the case of certain foods, e.g., margarine, where consumers demand artificial color. Housewives also frequently purchase certified color for use in home-prepared foods. In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box. Thus, it is in the interest of the consumer that the law be changed so as to make available an adequate supply of colors of the safety of which, for particular uses, the consumer can be assured.

2. Commercial interests: The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which, we believe, could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by this De-

partment. Hence, while, as a consumer protection agency, we are concerned first and foremost with the protection of consumer interests, equity to the commercial interests concerned is also a factor in the submission of this proposal. It should, however, be stressed in this connection that we would not agree to a dilution or relaxation of the limitations of the carefully designed transitional provisions of this bill with respect to color additives which have heretofore been in commercial use.

The technical provisions and approach of this bill are summarized in detail in the section-by-section analysis enclosed herewith. Suffice it to say here that the bill includes, with necessary adaptations, the substantive safeguards for public health and consumer protection contained in the Food Additives Amendment of 1958 so recently considered and adopted by the Congress.

SECTION-BY-SECTION ANALYSIS OF COLOR ADDITIVE AMENDMENTS OF 1959

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapter IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes)) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are, when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85-929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the food additives amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the above-mentioned changes; and contains transitional

provisions for commercially established colors.

II. SECTIONAL ANALYSIS

Title I. Amendments to Federal Food, Drug, and Cosmetic Act

Section 101 amends section 201 (the definitional section) of the basic act as follows:

Section 101(a) of the bill redesignates section 201(s) of the basic act, defining the term "food additive," by excluding color additives from the term "food additive." While coal-tar colors are already, by implication, outside the scope of the operative provisions of the food additives amendment of 1958 (Public Law 85-929), the express exclusion of "color additives" makes clear that, beginning with the date of enactment of this bill, all color additives (as defined in section 101(c) of the bill) will fall outside the scope of the provisions on "food additives."

Section 101(b) of the bill redesignates section 201(t) of the basic act as section 201(u) and extends the definition of "safe" to apply to the use of that term in section 706 of the basic act as amended by section 103(b) of the bill.

Section 101(c) of the bill adds to section 201 of the basic act a new subsection (t), which defines the term "color additive" as any dye, pigment, or other substance, either synthetic or extracted or otherwise derived, which is capable of imparting color to a food, drug, cosmetic, or the human body, but excluding any material that the Secretary, by regulation, determines is used solely for non-coloring purposes. (Black, white, and intermediate grays are expressly included in the term "color.")

Section 102(a):

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the proviso to section 402(c) with respect to the use of color on oranges (see Public Law 86-2). (Section 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (a) make the new provisions applicable to all color additives whether or not they are coal-tar colors; (b) extend them to the color additive itself before being added to food; and (c) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended section 706 of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (1), whereby a food which is a color additive is deemed misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

Section 102(b): Paragraph (1) amends section 501(a)(4) of the basic act to deem adulterated any drug containing a color additive solely for purposes of coloring, and any color additive which (with respect to its use in or on drugs) is intended solely for coloring purposes, if these are unsafe within the meaning of section 706(a) of the act. This would replace the present provision of section 501(a)(4), which deems a drug adulterated if it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified under section 504. (Section 504 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 502 of the basic act a new subsection (m) deeming misbranded a drug which is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with packaging and labeling requirements, if any, contained in regulations issued under section 706. (A color additive is, under the definition of "drug" in the basic act, itself a drug when intended for use as a component of drugs.)

Section 102(c): Paragraph (1) amends section 601(e) of the basic act so as to deem adulterated a cosmetic (other than a hair dye) which is, bears, or contains a color additive which is unsafe within the meaning of section 706 of the act. This would replace the existing provision, which deems adulterated a cosmetic (other than a hair dye) which bears or contains a coal-tar color other than one from a batch certified under section 604. (Section 604 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 602 of the act a new subsection (e) so as to deem misbranded a cosmetic which is a color additive (except a color additive for hair dyes) not packaged and labeled in accordance with packaging and labeling requirements, if any, under section 706. (Under the definition of "cosmetic" in the basic act, a color additive which is intended for use as a component of cosmetics is itself considered a cosmetic.)

Section 103: Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C., section 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

Section 706(a):

The basic operative provision of the section, this subsection deems a color additive unsafe for a particular use (or intended use) in or on food, drugs, or cosmetics, for the purposes of the application of sections 402(c), 501(a)(4), and 601(e), for the act

as amended by the bill, unless the color additive is listed under section 706(b) and complies with the conditions of use prescribed by the regulations listing the additive, and unless the additive is from a batch certified pursuant to regulations under section 706(c) or is exempted from the requirement of such certification. The single exception to these requirements is an exemption, to be provided by regulation (under sec. 706(f)), for color additives intended solely for investigational use by qualified experts.

Where a color additive is used in accordance with the Secretary's regulations, it is also exempted from the general provisions that deem adulterated any food (sec. 402(a)(1)) or cosmetic (sec. 601(a)) bearing or containing a poisonous or deleterious substance that may render it injurious to health. This exempting provision does not apply to hair dye (other than eyebrow and eyelash dye), since coal-tar hair dyes are not covered by section 601(e) of the act.

Section 706(b):

Paragraph (1). The Secretary is required to establish separate lists of color additives for use in respect to food, drugs, and cosmetics, to the extent that the additives are safe for use when employed in accordance with the regulations listing them.

Paragraph (2). The listing of an additive may be for general use in respect to food, or drugs, or cosmetics, or it may be for a more limited use.

Paragraph (3). The regulations listing the color additive must, to the extent deemed necessary to assure safety of use, prescribe tolerance limitations, other directions relating to the manner of adding or using the additive, labeling or packaging requirements for such additive, and other conditions.

Paragraph (4). A color additive may be listed for use only where it affirmatively appears that the additive may safely be used under the conditions to be prescribed by regulation; and that there are practicable methods for analyzing its contents, and for determining the identity and quantity of such additive in or on any article of food, drug, or cosmetic, and of any substance formed in an article because of the use of the additive. (Cf. secs. 409(b)(2)(D) and 409(c)(3) of the act, relating to food additives.)

Paragraph 5. In determining whether the use of a color additive is safe, the Secretary is required to consider, among other relevant factors, (a) the probable consumption of, or other relevant exposure from, the color additive and any other substance which is formed in the colored article by reason of the use of the color additive; (b) the cumulative effect (if any) of the additive in the diet, taking into account other substances in the diet which are chemically or pharmacologically related to the color additive; and (c) safety factors which are generally recognized by qualified experts as appropriate in using animal experimentation data as a basis for determining the safety of the color additive for the use or uses for which it is proposed to be listed. (This paragraph is modeled on section 409(c)(5) of the act, relating to food additives.)

Paragraph (6). The Secretary may not list a color additive for a proposed use if that use would promote deception of the consumer or otherwise result in a misbranding or adulteration within the meaning of other provisions of the act. (A similar provision is contained in section 409(c)(3)(B) of the act, for food additives.)

Paragraph (7). If a tolerance limitation is required to assure safety, a color additive may not be listed unless the data establish that, if used within a safe tolerance, the additive will achieve the intended physical or other technical effect; and the permissible tolerance may be set no higher than the level necessary to accomplish this effect.

This requirement is similar to that imposed on the Secretary by section 409(c)(4) of the act with respect to food additives.

Paragraph (8). Where, because of the aggregate quantity of a color additive (or pharmacologically related additives) likely to be involved, the Secretary cannot list the color (or colors) for all proposed uses, he may select among those uses or may apportion the aggregate allowable tolerance among them, subject to the paramount criterion of safety. For the purpose of such selection or allocation the bill provides for taking into account, among other relevant factors, the marketability of an article as affected by color, and industry dependence on the color uses involved; the quantities of color consumption involved in the various color uses; and the availability of other colors.

Section 706(c): Directs the Secretary to provide for the certification of batches of color additives and for exemption from the requirement of certification where unnecessary in the interest of the public health. Under this subsection the Secretary could provide for conditioning certification of batches of color additives on the keeping of records of disposal, as he does under existing law.

Section 706(d): This subsection, in general, incorporates, by reference, the procedures of section 701(e)-(g) which now govern coal-tar colors, except that it adopts the provisions as to "fair evaluation on the basis of the entire record" enacted by the food additives amendment of 1958.

In discussing the provisions of the food additives amendment of 1958 which the present bill incorporates by reference, Assistant Secretary Elliot L. Richardson, in a letter to the chairman of the House Committee on Interstate and Foreign Commerce, dated August 8, 1958, and reprinted in the CONGRESSIONAL RECORD, stated:

"The Secretary's action after hearing would have to be based upon a fair evaluation of the entire record at the hearing. On judicial review, the United States Court of Appeals would be required to sustain the findings of the Secretary if based upon a 'fair evaluation of the entire record at the hearing'; it would have to reverse the order of the Secretary if it is not 'based upon a fair evaluation of the entire record' or if it fails to include a statement setting forth in detail the findings and conclusions upon which the order is based. The 'fair evaluation' provision is quite applicable to the Department, because it is the standard to which we are accustomed to adhere" (CONGRESSIONAL RECORD, 85th Cong., 2d sess., Aug. 13, 1958, p. 16016).

The "fair evaluation of the entire record" standard thus is to govern the action of the Secretary after hearing, and to be used as a criterion by the reviewing court in passing on the validity of the Secretary's action, not merely as respects findings of fact but as respects his action as a whole. It, in effect, extends to rule making the approach to judicial review of administrative adjudication taken in *Universal Camera Corp. v. N.L.R.B.*, 340 U.S. 474 (1951), and attempts to encapsulate in a phrase the requirements of the Administrative Procedure Act as to fairness as opposed to arbitrariness, caprice, and abuse of discretion.

Section 706(e): This subsection contains the fee provision (with the reference to coal-tar colors amended to refer to color additives) contained in section 706 under existing law. Under the amended act fees for admitting a color to listing would necessarily include the cost of setting tolerance limitations authorized by section 706(b).

Section 706(f): The Secretary is required to provide, by regulation not subject to the above-mentioned procedure, for exempting from the operation of section 706 any color

additive or use thereof intended solely for investigational use by qualified experts, when such exemption is consistent with the public health. A similar exemption exists in section 409(i) of the act for food additives.

Section 104 extends section 301(j) of the basic act, which prohibits the revelation and the personal use of trade secrets acquired under the authority of various sections of the act (including section 409, relating to food additives), so as to include information obtained under the proposed section 706.

Section 105 contains appropriate changes of cross-references in, and other conforming amendments to, sections 301(i) (false use of required marks), 303(c) (3) (guarantee that coal-tar color is certified), and 402(d) (non-nutritive substances in confectionery) of the basic act.

Title II—Effective date, transitional provisions, and effect on other laws

Section 201 defines, for the purposes of title II, the term "basic act" as the Federal Food, Drug, and Cosmetic Act; the term "enactment date" as the date of enactment of the bill; and other terms, insofar as also used in the basic act (whether before or after enactment of the bill) as having the same meaning as they have, or had when in effect, under the basic act.

Section 202 makes the bill effective upon enactment, subject to the transitional provisions of section 203.

Section 203:

Subsection (a) (1) declares that this section is intended to make possible, for a reasonable interim period, through provisional listings, the continued use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific tests needed as a basis for making determinations with respect to the definitive listing of such additives under the basic act.

Subsection (a) (1) also directs that a provisional listing (which, while in effect, has the same effect as a listing under section 706 of the basic act) shall, if not sooner terminated, expire (i) on the "closing date" or (ii) on the effective date of the additive's listing under section 706, whichever date first occurs.

Subsection (a) (2) defines "closing date" as the last day of the 2½-year period beginning on the enactment date, except that, with respect to a particular provisional listing, the Secretary could postpone the original closing date for such period or periods, as he finds necessary to carry out the declared purpose of this section, if consistent with the objective of completing in good faith, as soon as practicable, the necessary scientific tests needed to make a determination with respect to listing under section 706 of the basic act. Such postponements could be terminated if they should not have been granted or on change of circumstances or on failure to submit required progress reports or meet other conditions.

Subsection (b): First, colors subject to those provisions of present law (secs. 406(b), 504, or 604, or the third proviso to sec. 402 (c)) which require the listing and certification of so-called coal-tar colors, are deemed provisionally listed for any use for which they were actually listed under these provisions on the day preceding the enactment date if a batch or batches of the color had been certified prior to that date. Second, a color additive which is either synthetic beta-carotene or which, on the date preceding the enactment date, was not within the purview of the so-called coal-tar color provisions of the law, is deemed provisionally listed under

the bill for any use of the color for which it was commercially used or sold prior to the enactment date. (It should be noted that the term "coal-tar color"—which, under existing law, is interpreted as including synthetic colors which, though not coal-tar derivatives, are so chemically structured as to be capable of being derived from coal tar—is not used in the bill. Synthetic beta-carotene is separately dealt with in the bill because its classification with coal-tar colors under existing law is in dispute and has been the subject of a hearing.)

Subsection (c) requires the Secretary, upon request, to list provisionally any color for any use for which it had been listed, and for which use a batch had actually been certified, under the above-mentioned coal-tar color provisions of existing law prior to the enactment date, although it was not so listed on the day preceding that date, if he deems such action consistent with protection of the public health.

Subsection (d) (1): The Secretary is directed, so far as practicable, (A) to promulgate and maintain current a list of color additives deemed provisionally listed, (B) to provide for provisional listing of color additives upon request in accordance with subsection (c), (C) to prescribe, if needed for public-health protection, temporary tolerance limitations (including zero tolerances) and other conditions of use for color additives provisionally listed, (D) to provide for the certification of batches of provisionally listed color additives (except that a color additive deemed provisionally listed under subsection (b) (2) shall be deemed exempt from certification while not subject to a tolerance); and (E) to provide for the termination of a provisional listing forthwith where necessary to protect the public health.

Subsection (d) (2): Regulations under this section are not subject to the procedural requirements of the Federal Food, Drug, and Cosmetic Act, but fees shall be charged (and be available for use) as though the regulations and other proceedings under this section had been under section 706 of the basic act as amended by the bill. On and after the starting date, provisional listing and certification under this section shall have the same effect as listing and certification under section 706 for the purpose of determining whether an article is adulterated or misbranded, but provisional listings and other actions under section 203 of the bill shall not give rise to any presumption or inference in section 706 proceedings.

Subsection (d) (3): In order that the Secretary may be able to promulgate and keep current a list of color additives deemed to be provisionally listed and to prescribe temporary tolerance limitations and other conditions of use with respect to those additives, he is directed to afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data submitted or otherwise before the Secretary do not reliably enable him to include a color in the published list of color additives deemed to be provisionally listed, or to ascertain the levels of use of such an additive prevailing prior to the enactment date, the Secretary is directed to fix a temporary zero tolerance for such colors or uses thereof until he deems a higher tolerance, or the absence of a tolerance limitation, consistent with the public interest.

Section 204 makes clear that the bill, when enacted, would not relieve any meat or meat food product or any person from any requirement under the Meat Inspection Act of March 4, 1907, as amended or extended (21 U.S.C. 71 et seq.), or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

AMENDMENT OF FEDERAL PROPERTY AND ADMINISTRATIVE SERVICES ACT OF 1949, RELATING TO OVERSEAS USE OF SURPLUS PROPERTY

Mr. ALLOTT. Mr. President, on behalf of myself, and the Senator from North Dakota [Mr. LANGER], I introduce, for appropriate reference, a bill to amend the Federal Property and Administrative Services Act of 1949, in order to make it possible for education and research organizations to avail themselves of surplus Government property, for use overseas. This amendment would not open the surplus property program to any new types of organizations, but merely would apply to the groups in this country already eligible to receive surplus property.

This amendment has become necessary, due to the fact that many of our institutions of higher learning have extended the scope of their activities into foreign lands since the act was passed by Congress in 1949; and for this highly important work they need the surplus equipment for which they are eligible at home.

The work of our universities in underprivileged areas abroad is highly important, because they are winning friends for the United States, counteracting anti-American influences, and winning the appreciation of friendly governments to whom they lend their training, skill, and dedication in bringing thousands of hinterland tribespeople into a new world of culture and economic development, as was so strikingly reported by the Reader's Digest, last August, in an article entitled "Two Thousand Tongues To Go."

It seems to me that the least we can do to encourage these contacts between our institutions of higher learning and foreign governments on the people-to-people plane is to permit these institutions to take abroad the surplus equipment that Congress has already authorized them to have, and which may well save the lives of young Americans laboring for human progress in the steaming jungles of Amazonia, the Philippines, New Guinea, and elsewhere. Certainly this will make their efforts more efficient, and will cost us nothing.

In conclusion, we should not overlook the fact that the valuable data and experience that these young Americans acquire while they are engaged in the educational and research activities in little explored tribal areas are of tremendous value to their educational institutions here in the United States, to improve the courses they offer. When we help others in such matters, we help ourselves.

Mr. President, several Senators have evidenced interest in this measure. I ask unanimous consent that the bill may remain at the desk through the close of business on June 22, in order that such additional Senators as may care to join in sponsoring the bill may do so.

The PRESIDENT pro tempore. The bill will be received and appropriately

referred; and, without objection, the bill will lie on the desk, as requested by the Senator from Colorado.

The bill (S. 2198) to amend the Federal Property and Administrative Service Act of 1949, introduced by Mr. ALLOTT (for himself and Mr. LANGER), was received, read twice by its title, and referred to the Committee on Government Operations.

PARTICIPATION IN RESETTLEMENT OF CERTAIN REFUGEES

Mr. KENNEDY. Mr. President, I introduce, for appropriate reference, a joint resolution to vest in the Attorney General permanent authority to cope with the continuing problem of the admission of refugees into the United States. This joint resolution is very similar to House Joint Resolution 397, introduced in the House of Representatives by Representative FRANCIS E. WALTER, chairman of the House Immigration Subcommittee.

The joint resolution expands the Attorney General's present authority under section 212(d)(5) of the Immigration and Nationality Act to parole aliens into the country for "emergent reasons." The most notable use ever made of this authority was the admission of some 32,000 Hungarian refugees following the ill-fated uprising in their homeland in the fall of 1956. This action was followed by the enactment last year of a special law granting the Hungarian refugees the privilege of remaining in the United States as permanent residents, if they are able to meet existing legal requirements for admission.

The two steps taken in regard to Hungarian refugees describe, in brief, the mechanics of the joint resolution. First, the Attorney General is given legislative direction to use his parole authority to admit refugees and escapees. Second, a procedure is established to grant aliens admitted under that authority the privilege of remaining in the United States as permanent residents, with the right, eventually, of acquiring U.S. citizenship.

Mr. President, World Refugee Year is about to begin in the United States by Presidential proclamation on July 1. Various proposals are being made for U.S. participation in a program during the coming year to help alleviate the world refugee problems. There could be no better occasion for the adoption of a permanent law concerning the admission of refugees into the United States.

The PRESIDENT pro tempore. The joint resolution will be received and appropriately referred.

The joint resolution (S.J. Res. 110) to enable the United States to participate in the resettlement of certain refugees, introduced by Mr. KENNEDY, was received, read twice by its title, and referred to the Committee on the Judiciary.

AMENDMENT OF SECOND LIBERTY BOND ACT—ADDITIONAL CO-SPONSORS OF BILL

Under authority of the order of the Senate of June 16, 1959, the names of

Mr. ENGLE and Mr. HUMPHREY were added as additional cosponsors of the bill (S. 2194) to amend section 21 of the Second Liberty Bond Act, as amended (31 U.S.C., sec. 757b), introduced by Mr. CLARK (for himself and other Senators) on June 16, 1959.

CIVILIAN USES OF ATOMIC ENERGY FOR MUTUAL DEFENSE PURPOSES—PROPOSED AMENDMENT OF AGREEMENT FOR COOPERATION WITH GREECE

Mr. PASTORE. Mr. President, on June 11, 1959, the President submitted to the Congress a proposed amendment between the United States and the Kingdom of Greece for cooperation on the uses of atomic energy for mutual defense purposes.

The proposed agreement is similar to other proposed agreements between the United States and the following NATO countries, the Federal Republic of Germany, the Kingdom of the Netherlands, and the Government of Turkey, which the President previously, on May 26, 1959, submitted to the Congress and which I placed in the RECORD on June 9. In order that all Members of the Congress and the public may have knowledge of the details of this latest agreement, I ask unanimous consent to have printed in the body of the RECORD the text of the proposed agreement for cooperation with the Kingdom of Greece, together with the accompanying recommendations of the Department of Defense, the State Department, and the Atomic Energy Commission, and the written approval of the President.

There being no objection, the proposed amendment and other material were ordered to be printed in the RECORD, as follows:

To the Congress of the United States:

In December 1957 the Heads of Government of the nation members of the North Atlantic Treaty Organization reached agreement in principle on the desirability of achieving the most effective pattern of NATO military defensive strength, taking into account the most recent developments in weapons and techniques. In enunciating this agreement in principle the Heads of Government made it clear that this decision was the result of the fact that the Soviet leaders, while preventing a general disarmament agreement, had left no doubt that the most modern and destructive weapons of all kinds were being introduced into the Soviet armed forces. The introduction of modern weapons into NATO forces should be no cause for concern on the part of other countries, since NATO is purely a defensive alliance.

It is our conviction and the conviction of our NATO allies that the introduction into NATO defenses of the most modern weapons available is essential in maintaining the strength necessary to the Alliance. Any alliance depends in the last analysis upon the sense of shared mutual interests among its members, and by sharing with our Allies certain training information we are demonstrating concretely our sense of partnership in NATO's defensive planning. Failure on our part to contribute to the improvement of the state of operational readiness of the forces of other members of NATO will only encourage the Soviet Union to believe that it can eventually succeed

in its goal of destroying NATO's effectiveness.

To facilitate the necessary cooperation on our part, legislation amending the Atomic Energy Act of 1954 was enacted during the last session of the Congress. Pursuant to that legislation agreements for cooperation were recently concluded with three of our NATO partners and submitted to the Congress on May 26. A similar agreement was also recently concluded with our NATO ally, the Kingdom of Greece. All of these agreements are designed to implement in important respects the agreed NATO program. This agreement with the Kingdom of Greece will enable the United States to cooperate effectively in mutual defense planning with Greece and in the training of Greek NATO forces in order that, if an attack on NATO should occur, under the direction of the Supreme Allied Commander for Europe Greek forces could effectively use nuclear weapons in their defense.

These agreements previously submitted and this Greek agreement represent only a portion of the work necessary for complete implementation of the decision taken by the North Atlantic Treaty Organization in December 1957. I anticipate the conclusion of similar agreements for cooperation with certain other NATO nations as the Alliance's defensive planning continues.

Pursuant to the Atomic Energy Act of 1954, as amended, I am submitting to each House of the Congress an authoritative copy of an agreement with the Kingdom of Greece. I am also transmitting a copy of the Acting Secretary of State's letter accompanying authoritative copies of the signed agreement, a copy of a joint letter from the Secretary of Defense and the Chairman of the Atomic Energy Commission recommending my approval of this document and a copy of my memorandum in reply thereto setting forth my approval.

Enclosures:

1. Agreement with the Kingdom of Greece.
2. Copy of a joint letter from the Secretary of Defense and the Chairman of the Atomic Energy Commission to the President.
3. Copy of the President's memorandum recording his approval.

THE WHITE HOUSE.

ATHENS, May 6, 1959.

His Excellency CONSTANTINE TSATSOS, Acting Foreign Minister, Athens.

EXCELLENCY: I have the honor to refer to the decisions taken at the North Atlantic Treaty heads of government meeting in December 1957 and to propose the following agreement between the Government of the United States of America and the Government of the Kingdom of Greece for cooperation on the uses of atomic energy for mutual defense purposes.

The Government of the United States of America and the Royal Hellenic Government.

Considering that they have concluded a mutual defense assistance agreement pursuant to which each Government will make available to the other equipment, materials, services, or other military assistance in accordance with such terms and conditions as may be agreed;

Considering that their mutual security and defense require that they be prepared to meet the contingencies of atomic warfare;

Considering that they are participating together in an international arrangement pursuant to which they are making substantial and material contributions to their mutual defense and security;

Recognizing that their common defense and security will be advanced by the exchange of information concerning atomic energy and by the transfer of certain types of equipment;

Believing that such exchange and transfer can be undertaken without risk to the defense and security of either country; and

Senate - Aug. 18, 1959

17. LANDS; LEASING. Conferees were appointed on H. R. 6939, to increase the area of public lands in Alaska which may be held under coal lease by any one person or firm. p. 14790
The Interior and Insular Affairs Committee voted to report (but did not actually report) with amendments S. 2181, to amend the Mineral Leasing Act of 1920, to modify oil, gas, coal, and other mineral leasing requirements and conditions. p. D782
S. 1514, to remove the limitation on the authorization for appropriations for the investigation of the water resources of Alaska, was made the unfinished business. pp. 14786, 14827
18. SCIENCE; RESEARCH. The Labor and Public Welfare Committee voted to report (but did not actually report) with amendment S. 2468, to amend the National Science Foundation Act of 1950 to strengthen scientific research. p. D783
19. COLOR ADDITIVES. The Labor and Public Welfare Committee voted to report (but did not actually report) S. 2197, the proposed Color Additives Amendments for 1959. p. D783
20. CREDIT UNIONS. Sen. Robertson announced that hearings will be held Fri., Aug. 21, on various bills to amend the Federal Credit Union Act. p. 14754
21. FOREIGN AID. Sen. Mansfield inserted an article and his correspondence with the State Department discussing the functions of the Inspector General of the foreign aid programs, and contended that under legislation recently enacted "The Inspector General is made responsible for the review of any and all aspects of the foreign aid program." pp. 14755-6
Sen. Schoeppel expressed his "apprehension and concern about the impact of our foreign aid and foreign trade policies upon American industry and upon American labor," and inserted several articles on the subject. pp. 14821-3
Sen. Mansfield inserted an article, "A Fund for Freedom," discussing the proposed establishment of an International Development Association to provide loans to aid underdeveloped countries. pp. 14826-7
22. LEGISLATIVE APPROPRIATION BILL FOR 1960. Received and agreed to the conference report on this bill, H. R. 7453 (pp. 14817-9). This bill will now be sent to the President.
23. PRICES; INFLATION. Sen. Kefauver stated that he was "disturbed" over what he termed a shift in emphasis made by the President's Cabinet Committee on Price Stability for Economic Growth from the need for price stability and inflation control to the need for economic growth, and he contended that the change in emphasis "reflects a weakening of the administration stand against inflation." He inserted a statement evaluating the use of certain price indexes in showing inflationary trends. pp. 14770-2
24. LEGISLATIVE PROGRAM. Sen. Johnson received consent to provide for the call of the calendar today (Aug. 19), beginning with S. 1711, the proposed International Food for Peace Act of 1959, and Sen. Johnson stated that it may be possible to consider a Public Law 480 bill and S. 2524, to prevent, under certain conditions, States or political subdivisions from imposing on a person a net income tax on income derived from interstate commerce. pp. 14749, 14815

ITEMS IN APPENDIX

25. FARM PROGRAM. Extension of remarks of Sen. Neuberger stating that "the American farmer, of late, has been suffering what might be called a bad press," and inserting an editorial, "The Farmer's Public Relations." pp. A7107-8

7. FAIRS; EXHIBITS. Passed as reported H. R. 8374, to authorize the appropriation of funds for participation of the Federal Government in the Century 21 Exposition in Seattle, Wash., beginning in 1961 (pp. 14850-63). The committee report on this bill states that this Department will provide exhibits on breeding and genetics, demonstration of new crops and new techniques in improving animals, and new food sources.
8. VETO AUTHORITY; BUDGETING. Rep. Curtin urged the enactment of legislation to "permit the President of the United States to approve and disapprove, separately, any individual items in appropriations bills passed by the Congress." p. 14902
9. LOBBYING. Received from the Clerk of the House and the Secretary of the Senate the quarterly report on lobbying. pp. 14907-38
10. FOOD STAMPS. The "Daily Digest" states that the Rules Committee deferred action on the granting of a rule on H. R. 1359, to provide for the establishment of a food-stamp plan for the distribution of \$1 billion worth of surplus food commodities a year to needy persons and families in the U. S. p. D786
11. SMALL BUSINESS. The Banking and Currency Committee voted to report (but did not actually report) H. R. 8599, to increase the authority of the Small Business Administration to make loans under its regular business program. p.D785
12. WATER DEVELOPMENT. The Judiciary Committee voted to report (but did not actually report) with amendment H. R. 5711, granting the consent and approval of Congress to the Wabash Valley Compact. p. D786
13. PERSONNEL; HEALTH. The Post Office and Civil Service Committee voted to report (but did not actually report) with amendment S. 2162, to provide a health benefits program for Government employees. p. D786

SENATE

14. HOUSING. Passed, 71 to 24, with amendments S. 2539, the new housing bill (pp. 14790-815). Earlier rejected, 28 to 67, a motion by Sen. Bennett to re-commit the bill to committee (p. 14812). See Digest 140 for the portion of the bill of interest to this Department.
15. FORESTRY; CONSERVATION. Received from the Secretary of the Army and the Secretary of Agriculture a letter reporting the intention of the Department of the Army and the Department of Agriculture to interchange jurisdiction of military and national forest lands within the Lucky Peak Reservoir project, Idaho, and the Boise National Forest (with an accompanying report). p. 14749
Sen. Dodd urged Congressional action on S. 2549, to declare a national policy on conservation, development, and utilization of natural resources, and stated that the bill would "provide for two important continuing groups to make annual studies and reports on the complete natural resource picture." He warned that "We have cut 90 percent of our virgin timber stand in the commercial forest area. The erosion of our soil and the consequent destruction of agricultural lands has been a national calamity." p. 14823
16. CONSERVATION CORPS. Sen. Mansfield inserted a letter from Sen. Murray to Secretary Benson urging the Secretary to restudy and support S. 812, the Youth Conservation Corps bill, and referring to the "excellent" photographs furnished by this Department, which "convinced ... at least five Senators ... of the merit of this bill." p. 14755

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sense of the Senate that the Rural Electrification Act should be interpreted so as to permit REA loans to cooperatives for service to persons who are without central-station service if they are located in an area generally served by a power supplier, or loans to persons without service who are located near a line of a power supplier. pp. 15309-10

4. RECLAMATION; WATER RESOURCES. The Judiciary Committee reported with amendments S. 1257, to approve the Wabash Valley Compact (S. Rept. 757). p. 15257

Passed with amendments S. 1136, to provide for transfer of title to irrigation distribution systems constructed under the Federal reclamation laws upon completion of repayment of the costs of the project. pp. 15296-8

Passed with amendment H. R. 968, to provide for construction by the Interior Department of the Bully Creek Dam and other facilities, Vale Federal reclamation project, Ore. pp. 15302-7

Passed without amendment S. 1221, to amend the act authorizing the Crooked River Federal reclamation project, Ore., in order to increase the capacity of certain project features for future irrigation of additional lands. pp. 15311-2

Passed without amendment S. 1514, to amend the act of Aug. 9, 1955, so as to eliminate restrictions on appropriations for investigations of water resources in Alaska. pp. 15301-2

5. COLOR ADDITIVES. The Labor and Public Welfare Committee reported with amendments S. 2197, to amend the Federal Food, Drug, and Cosmetic Act so as to authorize the use of color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing conditions under which such additives may be safely used (S. Rept. 795). p. 15257

6. APPROPRIATIONS. By a vote of 89 to 0, passed as reported H. R. 8575, the military construction appropriation bill for 1960. pp. 15284-90

7. FAIRS; INFORMATION. Passed with amendments H. R. 8374, to authorize appropriations for Federal participation in the Century 21 Exposition to be held in Seattle, Wash., in 1961 (including USDA participation). Consideration of a similar bill, S. 2065, was indefinitely postponed. pp. 15292-6

8. NOXIOUS PLANTS; LANDS. Passed without amendment S. 861, to authorize State officials to enter upon Federal lands within a State, under certain conditions, for the purpose of destroying noxious plants. pp. 15312-3

9. PROPERTY. Agreed to a House amendment to S. 900, to extend the authority of GSA to pay expenses in connection with the utilization of excess real property. The report of the House Government Operations Committee states that the amendment of the House is a "perfecting amendment since it clearly shows the extent of change to be made in existing law." p. 15314 This bill will now be sent to the President.

10. COMMITTEE EXPENDITURES. Agreed to S. Res. 161, to provide \$15,000 in additional funds for investigations by the Agriculture and Forestry

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF
BUDGET AND FINANCE

(For Department
Staff Only)

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HIGHLIGHTS: Senate passed bills to: Increase durum wheat allotments. Revise procedures for electing ASC committeemen. Senate agreed to measure expressing sense of Senate on GAO decision relative to certain REA loans. Sen. Symington urged enactment of food stamp plan.

SENATE

1. ASC COMMITTEES. Passed as reported S. 662, to revise the procedures relative to the selection of members and operation of State, county, and community ASC committees. pp. 15313-4
2. DURUM WHEAT. Passed as reported S. 1282, to require the Secretary to increase farm wheat acreage allotments in certain counties in N. Dak., Minn., S. Dak., and Calif. to the extent necessary to meet the demand for durum wheat. pp. 15299-300
3. ELECTRIFICATION. Agreed to as reported S. Res. 21, expressing it as the

COLOR ADDITIVE AMENDMENTS OF 1959

AUGUST 21, 1959.—Ordered to be printed

Mr. HILL, from the Committee on Labor and Public Welfare,
submitted the following

R E P O R T

[To accompany S. 2197]

The Committee on Labor and Public Welfare, to whom was referred the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill, as amended, do pass.

EXPLANATION

S. 2197 is designed to better protect the public health with respect to procedures necessary to assure the safety of color additives in foods, drugs, and cosmetics and to authorize the use of such color additives as have been predetermined to be perfectly safe in the amounts in which they are to be used. The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act with a scientifically sound and uniform system for the listing of color additives of any kind which may be safely used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Under existing law coal-tar colors may not be used in foods, drugs, or cosmetics unless they have been certified by the Food and Drug Administration as harmless and suitable for use. A recent Supreme Court decision has defined the "harmless" principle as meaning harmless regardless of the quantity of the coal-tar color which is being used. Thus, a color must be decertified if any quantity or

concentration of the color is harmful, even though in lesser concentrations it may be perfectly safe. Because of this principle, as defined by the Supreme Court, it has been necessary for the Food and Drug Administration to withdraw certification of seven food colors. Seventeen additional colors have been proposed for delisting. The effect of the application of the "harmless" principle in terms of existing law is to cause many of the coal-tar colors widely used in industry to be no longer available, and the number of colors withdrawn will eventually seriously handicap manufacturers of foods, drugs, and cosmetics in the production of products in the manner that is customary and usual.

Many food industries find themselves seriously affected by the delisting of colors. If additional proposed delistings are accomplished, similar effect is faced by drug and cosmetic industries. The very existence of many products depends upon the use of suitable color.

This legislation is necessary, because it will give the Secretary of Health, Education, and Welfare a flexibility, which he does not have under the present law, to certify coal-tar colors within tolerance limits which he determines are safe.

Two amendments to the bill as originally introduced were adopted by the committee. Both amendments were developed cooperatively by the committee staff, representatives of the industries concerned, and representatives of the Food and Drug Administration. Both have been declared acceptable by the Administration and by industry. Their objectives are, first, to permit those additives found "safe" by the Secretary under the procedures set forth in the Food Additives Amendments Act of 1958 to be considered "safe" when used as color additives, and, secondly, to relieve the Administration from the obligation of requiring the use of certain analytical methods, when, in its opinion, they are not needed.

The bill as amended has the endorsement of the Administration and of the following business groups which have concerned themselves with the legislation: The Certified Color Industry Committee, the Toilet Goods Association, the National Association of Margarine Manufacturers, the International Association of Ice Cream Manufacturers, the Grocery Manufacturers of America, and the National Confectioners Association.

S. 2197 was introduced at the request of the Department of Health, Education, and Welfare with the approval of the Bureau of the Budget.

DEPARTMENTAL COMMENT

Set forth below are, first, the letter of transmittal from Arthur S. Flemming, Secretary, Department of Health, Education, and Welfare, requesting the introduction of the legislation and setting forth the principal reasons which give rise to the need for immediate action in this field, and, second, letters dated August 7 and August 12, 1959, from Elliot L. Richardson, Assistant Secretary, Department of Health, Education, and Welfare, expressing approval of the committee amendments.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., May 29, 1959.

Hon. RICHARD M. NIXON,
President of the Senate,
Washington, D.C.

DEAR MR. PRESIDENT: We are enclosing herewith a draft bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on food, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. The bill may be referred to by the short title "Color Additive Amendments of 1959."

We respectfully urge the prompt consideration and enactment of this bill by Congress.

The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow us to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, we must ban the use of such a color completely as not being "harmless," if it is found to be toxic in the laboratory when fed in some concentrations, even though its actual level and manner of use may be completely safe; for externally applied drugs and cosmetics the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use is wholly safe.

The principle of allowing colors to be used under tolerance limitations was endorsed in 1956 by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the committee's report: "This committee feels compelled to indicate that certification of a compound as 'harmless and suitable for use' in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified."

2. The theoretically "perfect" public-health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only

“harmless” colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many, perhaps most, of the so-called colors on the list may in fact be toxic in some concentrations; yet we cannot take a particular color off the list until we establish its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which we could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors; there is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation (Public Law 86-2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring oranges, after previous adoption of the safe-for-use principle in the Food Additives Amendment of 1958 (Public Law 85-929). The only reason we had suggested to Congress that the emergency legislation for citrus red No. 2 have a termination date was that color legislation limited to particular colors and articles of food is discriminatory and that permanent legislation on this subject should contain additional safeguards. Moreover, Public Law 86-2 on its face indicates the expectation that Congress will before long address itself to the problem of general color legislation.

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

A more detailed explanation of the principal changes made in existing law, and the reasons therefor, is attached to the draft bill. There is also enclosed herewith a section-by-section analysis of the bill.

The establishment of a tolerance system in this field requires, to an extent not involved in a system without tolerance limitations, a program of education of the user industries and public, and a program of enforcement activities by a thoroughly trained corps of inspectors and analysts. The fee provisions, which are the same as those under existing law for coal-tar colors, would defray only the cost of maintaining the listing and certification service; additional costs would be incurred for the enforcement and informational activities required by the establishment of a tolerance system. Enclosed herewith, as required by Public Law 801, 84th Congress, are statements of cost estimates and personnel requirements which would be entailed.

We should appreciate it if you would refer the enclosed draft bill, with the accompanying material, to the appropriate committee for consideration.

The Bureau of the Budget advises that there is no objection to the presentation of this proposed legislation to the Congress for its consideration.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, August 7, 1959.

HON. LISTER HILL,
*Chairman, Committee on Labor and Public Welfare,
U.S. Senate, Washington, D.C.*

DEAR MR. CHAIRMAN: We understand that representatives of some of the industries that would be affected by S. 2197 (to be known as the Color Additive Amendments of 1959) have suggested to your committee an amendment to the bill relating to the requirements concerning analytical methods for color additives, and that an expression of our views on the amendment is desired.

Under the bill in its present form (p. 9, lines 3-16), the proposed section 706(b)(4) of the Federal Food, Drug, and Cosmetic Act would preclude the Secretary from listing a color additive for any use in or on food, drugs, or cosmetics unless the data before him establish—

“(A) that such use, under the conditions of use to be specified in the regulations, will be safe;

“(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

“(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive.”

The proposed amendment suggested by industry representatives would consolidate the matter contained in the above-quoted paragraphs (b) and (c) and, with appropriate editorial revision, transfer it to section 706(b)(5), which begins on the same page and enumerates some of the most important factors which the Secretary must consider in passing on the safety of a proposed use of a color additive. As so amended, section 706(b) (4) and (5), beginning on page 9, line 3, and ending on page 10, line 9, of the bill, would read as follows:

“(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe.

“(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

“(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

“(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

“(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

“(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.”

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analyses are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe.

The purpose of the requirement of the bill that there be practicable methods of analysis for determining the quantity of the pure dye and all intermediates and other impurities contained in a color additive is to enable the manufacturer of the color, and also this Department where we are asked to certify batches of color, to determine that the color in actual practice meets the requirements for purity and the definitional standards of our regulations and to facilitate enforcement. The purpose of the other requirements as to available practicable methods of analysis is to make possible effective enforcement of any conditions or limitations that may be put on the listing of a color for use in foods, drugs, or cosmetics. We, of course, regard practicability and facility of enforcement as essential elements of safety in determining whether a proposed use of a color additive is safe within the meaning of the bill.

There are many circumstances where it would be necessary to have practicable analytical methods for all or most of the above-mentioned purposes. We can, however, visualize some situations in which these analytical methods, or some of them, would not be necessary for any of the purposes which we have mentioned and would thus not be essential in the interest of sound public health protection. We therefore recognize that in requiring such analytical methods to be available in all cases without regard to actual need the original bill goes further than absolutely necessary for public health protection.

Under the proposed change, we would consider ourselves bound to require those analytical methods specified in the bill for which, on the basis of our general knowledge or on the basis of the particular situation, we find that there is a need for the above-mentioned purposes, or otherwise in the interest of safeguarding the public health, and we would therefore feel bound to refuse to list a color where such needed methods are not available. At the same time, the proposed amendment would relieve us of the necessity of imposing these requirements where they are not needed.

We therefore would not object to the proposed change in the bill.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., August 12, 1959.

HON. LISTER HILL,
U.S. Senate, Washington, D.C.

DEAR SENATOR HILL: Reference is made to S. 2197.

We have had an opportunity to consider the suggestions of members of your staff with regard to the status of coloring materials which are exempt from the provisions of the Food Additives Amendment, Public Law 85-929.

Materials which are generally recognized as safe for their intended use by experts qualified by training and experience to evaluate safety of foods are exempt from the provisions of the food additives amendment. We see no reason why such coloring materials as fall within this category and are found by the Secretary to be so classified should not be listed as suitable for use in food under the provisions of the color additive bill, S. 2197, and at the same time be exempt from the certification procedures provided for in that bill.

The language to reach this end is supplied herewith. We are satisfied that this same result would be obtained under the bill in any event.

Sincerely yours,

ELLIOTT L. RICHARDSON,
Assistant Secretary.

EXPLANATION OF PRINCIPAL FEATURES AND PURPOSES OF THE COLOR ADDITIVE AMENDMENTS OF 1959

The letter of transmittal from the Secretary of Health, Education, and Welfare, briefly summarizes the general objectives of S. 2197, the principal reasons which gave rise to it, and previous amendments

to the Federal Food, Drug, and Cosmetic Act which, in the case of food, show congressional endorsement of its key principle; i.e., recognition of the scientific soundness of considering the level and other conditions of use in determining the safety of a color additive. A fuller explanation is, however, necessary to an adequate understanding of the major provisions of the bill and their purposes against the background of existing law.

A. PRESENT LAW

Under present law, the treatment of color additives differs radically as between the so-called coal-tar colors and others. (For explanation of the technical difference between so-called coal-tar colors and others, see the discussion under "Major Changes Proposed.")

1. *Coal-tar colors*.—The act requires the Secretary to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, or cosmetics; and a food, drug, or cosmetic (other than a hair dye) is deemed adulterated if it bears or contains a coal-tar color other than from a certified batch (except that in the case of drugs this provision applies only where the coal-tar color is used for coloring purposes only). (See secs. 402(c), 406(b), 501(a)(4), 504, 601(e), 604, and 701 (e) and (f) of the act.) Under these provisions, the Secretary is without power to admit a color to listing under tolerance limitations (*Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958)).

2. *Other colors*.—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirement in the case of cosmetics or drugs (except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act).

On the other hand, with respect to their use in food, non-coal-tar coloring materials which are classed as "food additives" under the recent Food Additives Amendment of 1958 (Public Law 85-929) are subject to a requirement of official safety clearance, and to the establishment of tolerance limitations and other conditions of safe use where necessary for public health protection, except that colors which were in commercial use before January 1, 1958, are allowed a grace period for compliance; this period will expire not later than March 6, 1961. Such "food additive" colors, however, are not subject to any requirement of "batch" certification even if, in the view of the Administrator, this would be desirable for the protection of food processors and housewives using the color.

B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility*.—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics (other than hair dyes). This would be accomplished by excepting color additives (as defined in the bill) from the term "food additive"; repealing the present provisions for listing and certification

of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived. S. 2197 would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics.

2. *Safety-of-use principle.*—S. 2197 adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

3. *Comprehensive lists.*—S. 2197, however, retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as safe for use. While there was justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color.

4. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. The com-

mittee believes, however, that power to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color. One of the amendments adopted by the committee provides that a color additive deemed safe under the provisions of the Food Additives Amendment of 1956 shall be exempt from the requirement for certification.

5. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act, i.e., title I of the bill, would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The "commercially established" color additives falling under these transitional provisions are (a) those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill, and (b) those non-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic, except that in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

C. NEED FOR THE BILL

The interests of consumer protection and of the food, drug, cosmetic, and color industries combine to make urgent the need for enactment of this bill.

1. *Consumer protection*.—First. Under present law the Government has to perform extensive research to determine whether the colors now listed and being used are in fact harmless and suitable for use in food, drugs, and cosmetics. The bill would require industry to assume the burden of this testing, and would require the tests to be completed within 2½ years or, in individual cases, such additional testing period as is shown to be required and to be consistent with public-health protection. Further, it would allow the Secretary to place safe tolerance limitations on the amount of color that may be used and the products on which it may be used during this transition period; the Secretary has no such authority under present law.

Second. Other important aspects of consumer protection afforded by the bill are (a) that the pretesting requirement would be extended to those non-coal-tar colors, especially those used in cosmetics and drugs, to which it does not now apply, and (b) that the requirement of certification of batches of color, where necessary for the protection of the public health, would be extended to all colors.

Third. The use of color in foods, drugs, and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is, in many cases, also in the consumer's interest and affirmatively desired by consumers. This is obviously so not only in the case of cosmetics, many of which are designed and purchased for the very purpose of imparting color, but also in the case of certain foods, e.g., margarine, where consumers demand artificial color. Housewives also frequently purchase certified color for use in home-prepared foods. In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box. Thus, it is in the interest of the consumer that the law be changed so as to make available an adequate supply of colors of the safety of which, for particular uses, the consumer can be assured.

2. *Commercial interests*.—The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which, we believe, could be relieved for most established colors on a sound and permanent basis by enacting the provisions of S. 2197 without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Secretary.

The technical provisions and approach of this bill are summarized in detail in the section-by-section analysis which follows.

SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1959"

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes)) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are, when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85-929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the above-mentioned changes; and contains transitional provisions for commercially established colors.

II. SECTIONAL ANALYSIS

TITLE I—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

Section 101

Section 101 amends section 201 (the definitional section) of the basic act as follows:

Section 101(a) of the bill redesignates section 201(s) of the basic act, defining the term "food additive," by excluding color additives from the term "food additive." While coal-tar colors are already, by implication, outside the scope of the operative provisions of the Food Additives Amendment of 1958 (Public Law 85-929), the express exclusion of "color additives" makes clear that, beginning with the date of enactment of this bill, all color additives (as defined in sec. 101(c) of the bill) will fall outside the scope of the provisions on "food additives."

Section 101(b) of the bill redesignates section 201(t) of the basic act as section 201(u) and extends the definition of "safe" to apply to the use of that term in section 706 of the basic act as amended by section 103(b) of the bill.

Section 101(c) of the bill adds to section 201 of the basic act a new subsection (t), which defines the term "color additive" as any dye, pigment, or other substance, either synthetic or extracted or otherwise derived, which is capable of imparting color to a food, drug, cosmetic, or the human body, but excluding any material that the Secretary, by regulation, determines is used solely for noncoloring purposes. (Black, white, and intermediate grays are expressly included in the term "color.")

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by

the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86-2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (a) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (b) extend them to the color additive itself before being added to food; and (c) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (1), whereby a food which is a color additive is deemed misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

Section 102(b)

Paragraph (1) amends section 501(a)(4) of the basic act to deem adulterated any drug containing a color additive solely for purposes of coloring, and any color additive which (with respect to its use in or on drugs) is intended solely for coloring purposes, if these are unsafe within the meaning of section 706(a) of the act. This would replace the present provision of section 501(a)(4), which deems a drug adulterated if it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified under section 504. (Sec. 504 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 502 of the basic act a new subsection (m) deeming misbranded a drug which is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with packaging and labeling requirements, if any, contained in regulations issued under section 706. (A color additive is, under the definition of "drug" in the basic act, itself a drug when intended for use as a component of drugs.)

Section 102(c)

Paragraph (1) amends section 601(e) of the basic act so as to deem adulterated a cosmetic (other than a hair dye) which is, bears, or contains a color additive which is unsafe within the meaning of section 706 of the act. This would replace the existing provision, which deems adulterated a cosmetic (other than a hair dye) which bears or contains a coal-tar color other than one from a batch certified under section 604. (Sec. 604 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 602 of the act a new subsection (e) so as to deem misbranded a cosmetic which is a color additive (except a color additive for hair dyes) not packaged and labeled in accordance with packaging and labeling requirements, if any, under section 706. (Under the definition of "cosmetic" in the basic act, a color additive

which is intended for use as a component of cosmetics is itself considered a cosmetic.)

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

Section 706(a)

The basic operative provision of the section, this subsection deems a color additive unsafe for a particular use (or intended use) in or on food, drugs, or cosmetics for the purposes of the application of sections 402(c), 501(a)(4), and 601(e), of the act as amended by the bill, unless the color additive is listed under section 706(b) and complies with the conditions of use prescribed by the regulations listing the additive, and unless the additive is from a batch certified pursuant to regulations under section 706(c) or is exempted from the requirement of such certification. The single exception to these requirements is an exemption, to be provided by regulation (under sec. 706(f)), for color additives intended solely for investigational use by qualified experts.

Where a color additive is used in accordance with the Secretary's regulations, it is also exempted from the general provisions that deem adulterated any food (sec. 402(a)(1)) or cosmetic (sec. 601(a)) bearing or containing a poisonous or deleterious substance that may render it injurious to health. This exempting provision does not apply to hair dye (other than eyebrow and eyelash dye), since coal-tar hair dyes are not covered by section 601(e) of the act.

Section 706(b)

Paragraph (1): The Secretary is required to establish separate lists of color additives for use in respect to food, drugs, and cosmetics, to the extent that the additives are safe for use when employed in accordance with the regulations listing them.

Paragraph (2): The listing of an additive may be for general use in respect to food, or drugs, or cosmetics, or it may be for a more limited use.

Paragraph (3): The regulations listing the color additive must, to the extent deemed necessary to assure safety of use, prescribe tolerance limitations, other directions relating to the manner of adding or using the additive, labeling or packaging requirements for such additive, and other conditions.

Paragraph (4): A color additive may be listed for use only when it is shown that it may be safely used under the conditions prescribed by

regulation. A color additive that has been declared as safe and suitable for use as a food additive because it is generally recognized by qualified experts as safe will be listed for use in foods generally.

Paragraph (5): In determining whether a color additive is safe, the Secretary shall consider relevant factors such as probable total consumption, cumulative effect, and substances formed when the color is added to a food, drug, or cosmetic and safety factors required in using animal experimentation data. Practicable methods of analysis must be available when needed to insure safety and for enforcement of the regulation.

Paragraph (6): The Secretary may not list a color additive for a proposed use if that use would promote deception of the consumer or otherwise result in a misbranding or adulteration within the meaning of other provisions of the act. (A similar provision is contained in sec. 409(c)(3)(B) of the act, for food additives.)

Paragraph (7): If a tolerance limitation is required to assure safety, a color additive may not be listed unless the data establish that, if used within a safe tolerance, the additive will achieve the intended physical or other technical effect; and the permissible tolerance may be set no higher than the level necessary to accomplish this effect. This requirement is similar to that imposed on the Secretary by section 409(c)(4) of the act with respect to food additives.

Paragraph (8): Where, because of the aggregate quantity of a color additive (or pharmacologically related additives) likely to be involved, the Secretary cannot list the color (or colors) for all proposed uses, he may select among those uses or may apportion the aggregate allowable tolerance among them, subject to the paramount criterion of safety. For the purpose of such selection or allocation, the bill provides for taking into account, among other relevant factors, the marketability of an article as affected by color and industry dependence on the color uses involved; the quantities of color consumption involved in the various color uses; and the availability of other colors.

Section 706(c)

Directs the Secretary to provide for the certification of batches of color additives and for exemption from the requirement of certification where unnecessary in the interest of the public health. Under this subsection the Secretary could provide for conditioning certification of batches of color additives on the keeping of records of disposal, as he does under existing law. Colors exempt from the Food Additives Amendment because generally recognized as safe and listed as safe and suitable for use in food will be exempt from the certification requirement.

Section 706(d)

This subsection, in general, incorporates by reference the procedures of section 701 (e) to (g) which now govern coal-tar colors, except that it adopts the provisions as to "fair evaluation on the basis of the entire record" enacted by the Food Additives Amendment of 1958.

The provision of this bill with respect to judicial review is identical with the judicial review provision of the Food Additives Amendment of 1958. The Committee on Labor and Public Welfare, explaining this standard of judicial review in its report on the Food Additives Amendment of 1958, said: "The specific language of this bill—'fair evaluation of the entire record'—represents a new standard of judicial

review, which differs from the standard of 'substantial evidence on the record as a whole' that has heretofore been the criterion." The committee also referred to the judicial review provision as a "significant change in existing law."

Section 706(e)

This subsection contains the fee provision (with the reference to coal-tar colors amended to refer to color additives) contained in section 706 under existing law. Under the amended act fees for admitting a color to listing would necessarily include the cost of setting tolerance limitations authorized by section 706(b).

Section 706(f)

The Secretary is required to provide, by regulation not subject to the above-mentioned procedure, for exempting from the operation of section 706 any color additive or use thereof intended solely for investigational use by qualified experts, when such exemption is consistent with the public health. A similar exemption exists in section 409(i) of the act for food additives.

Section 104

Extends section 301(j) of the basic act, which prohibits the revelation and the personal use of trade secrets acquired under the authority of various sections of the act (including sec. 409, relating to food additives), so as to include information obtained under the proposed section 706.

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to, sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Section 201

Defines, for the purposes of title II, the term "basic act" as the Federal Food, Drug, and Cosmetic Act; the term "enactment date" as the date of enactment of the bill; and other terms, insofar as also used in the basic act (whether before or after enactment of the bill), as having the same meaning as they have, or had when in effect, under the basic act.

Section 202

Makes the bill effective upon enactment, subject to the transitional provisions of section 203.

Section 203

Subsection (a)(1) declares that this section is intended to make possible, for a reasonable interim period, through provisional listings, the continued use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific tests needed as a basis for making determinations with respect to the definitive listing of such additives under the basic act.

Subsection (a)(1) also directs that a provisional listing (which, while in effect, has the same effect as a listing under sec. 706 of the

basic act) shall, if not sooner terminated, expire (i) on the "closing date" or (ii) on the effective date of the additive's listing under section 706, whichever date first occurs.

Subsection (a)(2) defines "closing date" as the last day of the 2½-year period beginning on the enactment date, except that, with respect to a particular provisional listing, the Secretary could postpone the original closing date for such period or periods as he finds necessary to carry out the declared purpose of this section, if consistent with the objective of completing in good faith, as soon as practicable, the necessary scientific tests needed to make a determination with respect to listing under section 706 of the basic act. Such postponements could be terminated if they should not have been granted or on change of circumstances or on failure to submit required progress reports or meet other conditions.

Subsection (b): First, colors subject to those provisions of present law (secs. 406(b), 504, or 604, or the third proviso to sec. 402(c)) which require the listing and certification of so-called coal-tar colors, are deemed provisionally listed for any use for which they were actually listed under these provisions on the day preceding the enactment date if a batch or batches of the color had been certified prior to that date. Second, a color additive which is either synthetic beta-carotene or which, on the date preceding the enactment date, was not within the purview of the so-called coal-tar color provisions of the law, is deemed provisionally listed under the bill for any use of the color for which it was commercially used or sold prior to the enactment date. (It should be noted that the term "coal-tar color"—which under existing law is interpreted as including synthetic colors which, though not coal-tar derivatives, are so chemically structured as to be capable of being derived from coal tar—is not used in the bill. Synthetic beta-carotene is separately dealt with in the bill because its classification with coal-tar colors under existing law is in dispute and has been the subject of a hearing.)

Subsection (c) requires the Secretary, upon request, to list provisionally any color for any use for which it had been listed, and for which use a batch had actually been certified, under the above-mentioned coal-tar color provisions of existing law prior to the enactment date, although it was not so listed on the day preceding that date, if he deems such action consistent with protection of the public health.

Subsection (d)(1): The Secretary is directed, so far as practicable, (A) to promulgate and maintain current a list of color additives *deemed* provisionally listed, (B) to provide for provisional listing of color additives upon request in accordance with subsection (c), (C) to prescribe, if needed for public-health protection, temporary tolerance limitations (including zero tolerances) and other conditions of use for color additives provisionally listed, (D) to provide for the certification of batches of provisionally listed color additives (except that a color additive deemed provisionally listed under subsection (b)(2) shall be deemed exempt from certification while not subject to a tolerance); and (E) to provide for the termination of a provisional listing forthwith where necessary to protect the public health.

Subsection (d)(2): Regulations under this section are not subject to the procedural requirements of the Federal Food, Drug, and Cosmetic Act, but fees shall be charged (and be available for use) as though the regulations and other proceedings under this section had been under

section 706 of the basic act as amended by the bill. On and after the starting date, provisional listing and certification under this section shall have the same effect as listing and certification under section 706 for the purpose of determining whether an article is adulterated or misbranded, but provisional listings and other actions under section 203 of the bill shall not give rise to any presumption or inference in section 706 proceedings.

Subsection (d)(3): In order that the Secretary may be able to promulgate and keep current a list of color additives deemed to be provisionally listed and to prescribe temporary tolerance limitations and other conditions of use with respect to those additives, he is directed to afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data submitted or otherwise before the Secretary do not reliably enable him to include a color in the published list of color additives *deemed* to be provisionally listed, or to ascertain the levels of use of such an additive prevailing prior to the enactment date, the Secretary is directed to fix a temporary zero tolerance for such colors or uses thereof until he deems a higher tolerance, or the absence of a tolerance limitation, consistent with the public interest.

Section 204

Makes clear that the bill, when enacted, would not relieve any meat or meat food product or any person from any requirement under the Meat Inspection Act of March 4, 1907, as amended or extended (21 U.S.C. 71 et seq.), or the Poultry Products Inspection Act (21 U.S. C. 451 et seq.).

CHANGES IN EXISTING LAW

In compliance with subsection (4) of rule XXIX of the Standing Rules of the Senate, changes in existing law made by the bill, as reported, are shown as follows: (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italics, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT, AS AMENDED

AN ACT To prohibit the movement in interstate commerce of adulterated and misbranded food, drugs, devices, and cosmetics, and for other purposes

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled,

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

* * * * *

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the

characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, though either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity; or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

[(3) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).]

(3) a color additive: or

(4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

[(t) The term "safe," as used in paragraph (s) of this section and in section 409, has reference to the health of man or animal.]

(t) (1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

(u) The term "safe", as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

* * * * *

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other

identification device authorized or required by regulations promulgated under the provisions of section [404, 406(b), 504, 506, 507, or 604] 404, 506, 507, or 706.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, [or 704] 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

* * * * *

PENALTIES

SEC. 303. * * *

* * * * *

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a [coal-tar] color additive not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the [coal-tar] color additive, to the effect that such color was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act;

* * * * *

CHAPTER IV—FOOD

* * * * *

ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance, [except a pesticide chemical in or on a raw agricultural commodity and ex-

cept a food additive) **1** (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive) which is unsafe within the meaning of section 406, or

* * * * *

(B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409 ^{2a}.

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

1(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: . . . *Provided* . . . That, without regard to the requirements of sections 406(b) and 701(e), the Secretary shall promptly establish, and may from time to time amend, regulations (1) prescribing the conditions (including quantitative tolerance limitations) under which the coal-tar color known as Citrus Red No. 2 (more particularly to be defined in such regulations) may be safely used in coloring the skins of oranges which are not intended or used for processing (or, if so used, are oranges designated in the trade as "packing house elimination"), and which meet minimum maturity standards established by or under the laws of the States in which the oranges are grown, (2) providing for separately listing such color solely for such use on such oranges, and (3) providing for the certification of batches of such color, with or without harmless diluents, for such restricted use; and such oranges, if colored prior to September 1, 1961, and to the enactment by the Congress (subsequent to the date of enactment of this proviso) of general legislation for the listing and certification of food color additives under safe tolerances, in conformity with this proviso and such regulations, with Citrus Red No. 2 from a batch certified in accordance with such regulations, shall not be deemed to be adulterated within the meaning of this paragraph. **1**

(c) *If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).*

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except [harmless coloring] *authorized coloring*, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

* * * * *

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

* * * * *

(l) *If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.*

* * * * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. [(a)]

* * * * *

[(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.]

* * * * *

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a) (1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of a poisonous or deleterious substance which may render the contents injurious to health; or [(4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504.] (4) *if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).*

* * * * *

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

* * * * *

(m) *If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.*

* * * * *

[CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

[SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.]

* * * * *

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. A cosmetic shall be deemed to be adulterated—

* * * * *

[(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.]

(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

* * * * *

(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).

* * * * *

[CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

[SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. * * *

* * * * *

(e) (1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), [406 (a) or (b)] 406, 501(b), or 502 (d) or (h), [504, or 604] of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein, but not prior to the day following the last day on which objections may be filed under such paragraph.

* * * * *

[COST OF CERTIFICATION OF COAL-TAR COLORS

[SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.]

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

When Color Additives Deemed Unsafe

SEC. 706. (a) *A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—*

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii), has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section. While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection

(f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

Listing of Colors

(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used, specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term "food additive" because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color addi-

tives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

Certification of Colors

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason

of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

Procedure for Issuance, Amendment, or Repeal of Regulations

(d) The provisions of section 701(e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsections (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f)(2); and

(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

Fees

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Exemptions

(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.





Calendar No. 807

86TH CONGRESS
1ST SESSION

S. 2197

[Report No. 795]

IN THE SENATE OF THE UNITED STATES

JUNE 17, 1959

Mr. HILL (for himself and Mr. GOLDWATER) introduced the following bill; which was read twice and referred to the Committee on Labor and Public Welfare

AUGUST 21, 1959

Reported by Mr. HILL, with amendments

[Omit the part struck through and insert the part printed in italic]

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

- 1 *Be it enacted by the Senate and House of Representa-*
2 *tives of the United States of America in Congress assembled,*
3 That this Act may be cited as the "Color Additive Amend-
4 ments of 1959".

1 TITLE I—AMENDMENTS TO THE FEDERAL FOOD,
2 DRUG, AND COSMETIC ACT

3 DEFINITIONS

4 SEC. 101. Section 201, as amended, of the Federal
5 Food, Drug, and Cosmetic Act is further amended as
6 follows:

7 (a) Paragraph (s) of such section (defining the term
8 “food additive”) is amended by redesignating clause (3) as
9 clause (4), and by inserting immediately before clause (4),
10 as so redesignated, the following new clause:

11 “(3) a color additive; or”.

12 (b) Paragraph (t) of such section is redesignated and
13 otherwise amended to read as follows:

14 “(u) The term ‘safe’, as used in paragraph (s) of this
15 section and in sections 409 and 706, has reference to the
16 health of man or animal.”

17 (c) There is inserted, immediately after paragraph (s)
18 of such section, the following new paragraph:

19 “(t) (1) The term ‘color additive’ means a material
20 which—

21 “(A) is a dye, pigment, or other substance made
22 by a process of synthesis or similar artifice, or extracted,
23 isolated, or otherwise derived, with or without inter-
24 mediate or final change of identity, from a vegetable,
25 animal, mineral, or other source, and

“(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto; except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

9 “(2) The term ‘color’ includes black, white, and inter-
10 mediate grays.”

11 COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE
12 ADULTERATED OR MISBRANDED FOODS, DRUGS, OR COS-
13 METICS

14 Food

15 SEC. 102. (a) (1) Clause (2) (A) of section 402 (a),
16 as amended, of such Act (relating to food deemed adulter-
17 ated by reason of unsafe additives) is further amended by
18 striking out the matter within the parentheses and inserting
19 in lieu thereof the following: "other than one which is (i) a
20 pesticide chemical in or on a raw agricultural commodity;
21 (ii) a food additive; or (iii) a color additive".

(2) Section 402 (c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

1 “(c) If it is, or it bears or contains, a color additive
2 which is unsafe within the meaning of section 706 (a).”

3 (3) Section 403 of such Act (relating to the circum-
4 stances under which food is deemed misbranded) is amended
5 by adding at the end thereof the following new paragraph:

6 “(1) If it is a color additive, unless its packaging and
7 labeling are in conformity with such packaging and labeling
8 requirements, applicable to such color additive, as may be
9 contained in regulations issued under section 706.”

Drugs

11 (b) (1) Clause (4) of section 501 (a) of such Act (re-
12 lating to drugs deemed adulterated by reason of uncertified
13 coal-tar color) is amended to read as follows: “(4) if (A)
14 it is a drug which bears or contains, for purposes of color-
15 ing only, a color additive which is unsafe within the mean-
16 ing of section 706 (a), or (B) it is a color additive the
17 intended use of which in or on drugs is for purposes of
18 coloring only and is unsafe within the meaning of section
19 706 (a).”

20 (2) Section 502 of such Act (relating to the circum-
21 stances under which drugs are deemed misbranded) is
22 amended by adding at the end thereof the following new
23 paragraph:

24 “(m) If it is a color additive the intended use of which

1 in or on drugs is for the purpose of coloring only, unless its
2 packaging and labeling are in conformity with such packaging
3 and labeling requirements, applicable to such color additive,
4 as may be contained in regulations issued under section 706.”

Cosmetics

6 (c) (1) Section 601 (e) of such Act (relating to cos-
7 metics, other than hair dyes, deemed adulterated by reason
8 of uncertified coal-tar color) is amended to read as follows:

9 “(e) If it is not a hair dye and it is, or it bears or
10 contains, a color additive which is unsafe within the meaning
11 of section 706 (a).”

12 (2) Section 602 of such Act (relating to the circum-
13 stances under which cosmetics shall be deemed to be mis-
14 branded) is amended by adding at the end thereof the
15 following new paragraph:

16 “(e) If it is a color additive, unless its packaging and
17 labeling are in conformity with such packaging and labeling
18 requirements, applicable to such color additive, as may be
19 contained in regulations issued under section 706. This
20 paragraph shall not apply to packages of color additives
21 which, with respect to their use for cosmetics, are marketed
22 and intended for use only in or on hair dyes (as defined in
23 the last sentence of section 601 (a)).”

1 REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR
2 FOODS, DRUGS, AND COSMETICS

3 SEC. 103. (a) Such Act is further amended by—

4 (1) repealing subsection (b) of section 406 and
5 striking out the subsection designation “(a)” after
6 “SEC. 406.” in such section;

7 (2) repealing section 504;

8 (3) repealing section 604; and

9 (4) amending section 701 (e) by (A) striking out
10 “406 (a) or (b)” and inserting in lieu thereof “406”;
11 (B) striking out “504, or 604,”; and (C) inserting the
12 word “or” after “501 (b),”.

13 (b) Section 706 of such Act is amended to read as fol-
14 lows:

15 “LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR
16 FOODS, ~~DRUGS~~ DRUGS, AND COSMETICS

17 “When Color Additives Deemed Unsafe

18 “SEC. 706. (a) A color additive shall, with respect to
19 any particular use (for which it is being used or intended
20 to be used or is represented as suitable) in or on food or
21 drugs or cosmetics, be deemed unsafe for the purposes of the
22 application of section 402 (c), section 501 (a) (4), or
23 section 601 (e), as the case may be, unless—

24 “(1) (A) there is in effect, and such additive and
25 such use are in conformity with, a regulation issued

under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) ~~has~~ *has*, with respect to such use, been exempted by the Secretary from the requirement of certification; or

“(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402 (a) if such article is a food, or within the meaning of section 601 (a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601 (a)).

“Listing of Colors

“(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives

1 for use in or on cosmetics, if and to the extent that such
2 additives are suitable and safe for any such use when em-
3 ployed in accordance with such regulations.

4 “(2) (A) Such regulations may list any color additive
5 for use generally in or on food, or in or on drugs, or in or
6 on cosmetics, if the Secretary finds that such additive is
7 suitable and may safely be employed for such general use.

8 “(B) If the data before the Secretary do not establish
9 that the additive satisfies the requirements for listing such
10 additive on the applicable list pursuant to subparagraph
11 (A) of this paragraph, or if the proposal is for listing such
12 additive for a more limited use or uses, such regulations
13 may list such additive only for any more limited use or
14 uses for which it is suitable and may safely be employed.

15 “(3) Such regulations shall, to the extent deemed neces-
16 sary by the Secretary to assure the safety of the use or uses
17 for which a particular color additive is listed, prescribe the
18 conditions under which such additive may be safely em-
19 ployed for such use or uses (including, but not limited to,
20 specifications, hereafter in this section referred to as toler-
21 ance limitations, as to the maximum quantity or quantities
22 which may be used or permitted to remain in or on the article
23 or articles in or on which it is ~~used~~, *used*; specifications as to
24 the manner in which such additive may be added to or used

1 in or on such article or articles; and directions or other label-
2 ing or packaging requirements for such additive).

3 “(4) The Secretary shall not list a color additive under
4 this section for a proposed use unless the data before him
5 established—

6 “(A) that such use, under the conditions of use
7 to be specified in the regulations, will be safe;

8 “(B) that practicable methods of analysis exist for
9 determining the quantity of the pure dye and all inter-
10 mediates and other impurities contained in such color
11 additive; and

12 “(C) that practicable methods exist for determin-
13 ing the identity and quantity (i) of such additive in or
14 on any article of food, drug, or cosmetic, and (ii) of
15 any substance formed in or on such article because of
16 the use of such additive.

17 “(5) (A) In determining, for the purposes of this sec-
18 tion, whether a proposed use of a color additive is safe, the
19 Secretary shall consider, among other relevant factors—

20 “(i) the probable consumption of, or other relevant
21 exposure from, the additive and of any substance formed
22 in or on food, drugs, or cosmetics because of the use of
23 the additive,

1 “(ii) the cumulative effect, if any, of such additive
2 in the diet of man or animals, taking into account the
3 same or any chemically or pharmacologically related
4 substance or substances in such diet; and

5 “(iii) safety factors which, in the opinion of experts
6 qualified by scientific training and experience to evaluate
7 the safety of color additives for the use or uses for which
8 the additive is proposed to be listed, are generally recog-
9 nized as appropriate for the use of animal experimenta-
10 tion data.

11 “(4) *The Secretary shall not list a color additive under*
12 *this section for a proposed use unless the data before him*
13 *establish that such use, under the conditions of use specified*
14 *in the regulations, will be safe: Provided, however, That a*
15 *color additive shall be deemed to be suitable and safe for the*
16 *purpose of listing under this subsection for use generally*
17 *in or on food, while there is in effect a published finding*
18 *of the Secretary declaring such substance exempt from the*
19 *term ‘food additive’ because of its being generally recognized*
20 *by qualified experts as safe for its intended use, as provided*
21 *in section 201(s).*

22 “(5) *In determining, for the purposes of this section,*
23 *whether a proposed use of a color additive is safe, the Sec-*
24 *retary shall consider, among other relevant factors—*

1 “(A) the probable consumption of, or other relevant
2 exposure from, the additive and of any substance formed
3 in or on food, drugs, or cosmetics because of the use of
4 the additive;

5 “(B) the cumulative effect, if any, of such additive
6 in the diet of man or animals, taking into account the
7 same or any chemically or pharmacologically related
8 substance or substances in such diet;

9 “(C) safety factors which, in the opinion of ex-
10 perts qualified by scientific training and experience to
11 evaluate the safety of color additives for the use or uses
12 for which the additive is proposed to be listed, are gen-
13 erally recognized as appropriate for the use of animal
14 experimentation data; and

15 “(D) the availability of any needed practicable
16 methods of analysis for determining the identity and
17 quantity of (i) the pure dye and all intermediates and
18 other impurities contained in such color additive, (ii)
19 such additive in or on any article of food, drug, or cos-
20 metic, and (iii) any substance formed in or on such
21 article because of the use of such additive.”

22 “(6) The Secretary shall not list a color additive under
23 this subsection for a proposed use if the data before him show
24 that such proposed use would promote deception of the con-

1 sumer in violation of this Act or would otherwise result in
2 misbranding or adulteration within the meaning of this
3 Act.

4 “(7) If, in the judgment of the Secretary, a tolerance
5 limitation is required in order to assure that a proposed use
6 of a color additive will be safe, the Secretary—

7 “(A) shall not list the additive for such use if he
8 finds that the data before him do not establish that such
9 additive, if used within a safe tolerance limitation, would
10 achieve the intended physical or other technical effect;
11 and

12 “(B) shall not fix such tolerance limitation at a
13 level higher than he finds to be reasonably required to
14 accomplish the intended physical or other technical
15 effect.

16 “(8) If, having regard to the aggregate quantity of
17 color additive likely to be consumed in the diet or to be ap-
18 plied to the human body, the Secretary finds that the data
19 before him fail to show that it would be safe and otherwise
20 permissible to list a color additive (or pharmacologically re-
21 lated color additives) for all the uses proposed therefor and
22 at the levels of concentration proposed, the Secretary shall,
23 in determining for which use or uses such additive (or such
24 related additives) shall be or remain listed, or how the
25 aggregate allowable safe tolerance for such additive or addi-

1 tives shall be allocated by him among the uses under con-
2 sideration, take into account, among other relevant factors
3 (and subject to the paramount criterion of safety), (A) the
4 relative marketability of the articles involved as affected by
5 the proposed uses of the color additive (or of such related
6 additives) in or on such articles, and the relative dependence
7 of the industries concerned on such uses; (B) the relative
8 aggregate amounts of such color additive which he estimates
9 would be consumed in the diet or applied to the human body
10 by reason of the various uses and levels of concentration
11 proposed; and (C) the availability, if any, of other color
12 additives suitable and safe for one or more of the uses
13 proposed.

14 "Certification of Colors

15 "(c) The Secretary shall further, by regulation, pro-
16 vide (1) for the certification, with safe diluents or without
17 diluents, of batches of color additives listed pursuant to sub-
18 section (b) and conforming to the requirements for such
19 additives established by regulations under such subsection
20 and this subsection, and (2) for exemption from the require-
21 ment of certification in the case of any such additive, or any
22 listing or use thereof, for which he finds such requirement
23 not to be necessary in the interest of the protection of the
24 public health: *Provided, That, with respect to any use in*

1 *or on food for which a listed color additive is deemed to be*
2 *safe by reason of the proviso to paragraph (4) of subsection*
3 *(b), the requirement of certification shall be deemed not to*
4 *be necessary in the interest of public health protection.*

5 “Procedure for Issuance, Amendment, or Repeal of
6 Regulations

7 “(d) The provisions of section 701 (e), (f), and (g)
8 of this Act shall apply to and in all respects govern proceed-
9 ings for the issuance, amendment, or repeal of regulations
10 under subsections (b), (c), or (e) of this section (including
11 judicial review of the Secretary’s action in such proceedings)
12 and the admissibility of transcripts of the record of such pro-
13 ceedings in other proceedings, except that—

14 “(1) the Secretary’s order after public hearing
15 (acting upon objections filed to an order made prior to
16 hearing) shall be subject to the requirements of section
17 409 (f) (2) ; and

18 “(2) the scope of judicial review of such order shall
19 be in accordance with the third sentence of paragraph
20 (2), and with the provisions of paragraph (3), of
21 section 409 (g) .

22 “Fees

23 “(e) The admitting to listing and certification of color
24 additives, in accordance with regulations prescribed under
25 this Act, shall be performed only upon payment of such fees,

1 which shall be specified in such regulations, as may be neces-
2 sary to provide, maintain, and equip an adequate service for
3 such purposes.

4 "Exemptions

5 " (f) The Secretary shall by regulation (issued without
6 regard to subsection (d)) provide for exempting from the
7 requirements of this section any color additive or any specific
8 type of use thereof, and any article of food, drug, or cosmetic
9 bearing or containing such additive, intended solely for in-
10 vestigational use by qualified experts when in his opinion such
11 exemption is consistent with the public health."

12 CONFIDENTIALITY OF TRADE SECRETS

13 SEC. 104. Section 301 (j) , as amended, of such Act,
14 prohibiting disclosure of trade secrets, is amended by strik-
15 ing out "or 704" and inserting in lieu thereof "704, or 706".

16 CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

17 SEC. 105. Such Act is further amended by—

18 (a) striking out, in section 301 (i) thereof (relat-
19 ing to forgery or unauthorized use of certain identifica-
20 tion ~~deviees~~, *devices*), "404, 406 (b) , 504, 506, 507, or
21 604", and inserting in lieu thereof "404, 506, 507, or
22 706";

23 (b) (1) striking out, in clause (3) of section 303

24 (c) (relating to color manufacturer's guarantee), the
25 word "coal-tar" wherever it appears in such clause,

1 and (2) inserting after the word "color", wherever it
2 appears in such clause, the word "additive"; and

3 (c) striking out "harmless coloring" in section
4 402 (d) (relating to non-nutritive substances in confec-
5 tionery) and inserting in lieu thereof "authorized col-
6 oring".

7 TITLE II—EFFECTIVE DATE, TRANSITIONAL
8 PROVISIONS, AND EFFECT ON OTHER LAWS

9 DEFINITIONS

10 SEC. 201. As used in this title, the term "basic Act"
11 means the Federal Food, Drug, and Cosmetic Act; the term
12 "enactment date" means the date of enactment of this Act;
13 and other terms, insofar as also used in the basic Act
14 (whether before or after enactment of this Act) shall have
15 the same meaning as they have, or had when in effect,
16 under the basic Act.

17 EFFECTIVE DATE

18 SEC. 202. This Act shall, subject to the provisions of
19 section 203, take effect on the enactment date.

20 PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED
21 COLORS

22 SEC. 203. (a) (1) The purpose of this section is to
23 make possible, on an interim basis for a reasonable period,
24 through provisional listings, the use of commercially estab-
25 lished color additives to the extent consistent with the pub-

1 lic health, pending the completion of the scientific investi-
2 gations needed as a basis for making determinations as to
3 listing of such additives under the basic Act as amended
4 by this Act. A provisional listing (including a deemed
5 provisional listing) of a color additive under this section for
6 any use shall, unless sooner terminated or expiring under
7 the provisions of this section, expire (A) on the closing
8 date (as defined in paragraph (2) of this subsection) or
9 (B) on the effective date of a listing of such additive for
10 such use under section 706 of the basic Act, whichever
11 date first occurs.

12 (2) For the purposes of this section, the term "closing
13 date" means (A) the last day of the two and one-half
14 year period beginning on the enactment date or (B), with
15 respect to a particular provisional listing (or deemed pro-
16 visional listing) of a color additive or use thereof, such later
17 closing date as the Secretary may from time to time establish
18 pursuant to the authority of this paragraph. The Secretary
19 may by regulation, upon application of an interested person
20 or on his own initiative, from time to time postpone the
21 original closing date with respect to a provisional listing (or
22 deemed provisional listing) under this section of a specified
23 color additive, or of a specified use or uses of such additive,
24 for such period or periods as he finds necessary to carry
25 out the purpose of this section, if in the Secretary's judg-

1 ment such action is consistent with the objective of carry-
2 ing to completion in good faith, as soon as reasonably prac-
3 ticable, the scientific investigations necessary for making
4 a determination as to listing such additive, or such specified
5 use or uses thereof, under section 706 of the basic Act. The
6 Secretary may terminate a postponement of the closing
7 date at any time if he finds that such postponement should
8 not have been granted, or that by reason of a change in
9 circumstances the basis for such postponement no longer
10 exists, or that there has been a failure to comply with a
11 requirement for submission of progress reports or with other
12 conditions attached to such postponement.

13 (b) Subject to the other provisions of this section—

14 (1) any color additive which, on the day preceding
15 the enactment date, was listed and certifiable for any
16 use or uses under section 406 (b), 504, or 604, or under
17 the third proviso of section 402 (c), of the basic Act,
18 and of which a batch or batches had been certified for
19 such use or uses prior to the enactment date, and

20 (2) any color additive which was commercially
21 used or sold prior to the enactment date for any use or
22 uses in or on any food, drug, or cosmetic, and which
23 either (A) on the day preceding the enactment date
24 was not a material within the purview of any of the pro-

visions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene, shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406 (b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a

1 particular use shall, in any proceeding under the basic
2 Act, be conclusive evidence that such provisional listing
3 is in effect;

4 (B) provide for the provisional listing of the color
5 additives and particular uses thereof specified in sub-
6 section (c) ;

7 (C) provide, with respect to particular uses for
8 which color additives are or are deemed to be provision-
9 ally listed, such temporary tolerance limitations (in-
10 cluding such limitations at zero level) and other condi-
11 tions of use and labeling or packaging requirements, if
12 any, as in his judgment are necessary to protect the
13 public health pending listing under section 706 of the
14 basic Act;

15 (D) provide for the certification of batches of such
16 color additives (with or without diluents) for the uses
17 for which they are so listed or deemed to be listed under
18 this section, except that such an additive which is a
19 color additive deemed provisionally listed under sub-
20 section (b) (2) of this section shall be deemed exempt
21 from the requirement of such certification while not sub-
22 ject to a tolerance limitation; and

23 (E) provide for the termination of a provisional
24 listing (or deemed provisional listing) of a color addi-
25 tive or particular use thereof forthwith whenever in his

1 judgment such action is necessary to protect the public
2 health.

3 (2) (A) Regulations under this section shall, from time
4 to time, be issued, amended, or repealed by the Secretary
5 without regard to the requirements of the basic Act, but for
6 the purposes of the application of section 706 (e) of the basic
7 Act (relating to fees) and of determining the availability of
8 appropriations of fees (and of advance deposits to cover
9 fees), proceedings, regulations, and certifications under this
10 section shall be deemed to be proceedings, regulations, and
11 certifications under such section 706.

12 (B) On and after the enactment date, regulations, pro-
13 visional listings, and certifications (or exemptions from cer-
14 tification) in effect under this section shall, for the purpose
15 of determining whether an article is adulterated or mis-
16 branded within the meaning of the basic Act by reason of its
17 being, bearing, or containing a color additive, have the same
18 effect as would regulations, listings, and certifications (or
19 exemptions from certification) under section 706 of the basic
20 Act. A regulation, provisional listing or termination
21 thereof, tolerance limitation, or certification or exemption
22 therefrom, under this section shall not be the basis for any
23 presumption or inference in any proceeding under section
24 706 (b) or (c) of the basic Act.

25 (3) For the purpose of enabling the Secretary to carry

1 out his functions under paragraph (1) (A) and (C) with
2 respect to color additives deemed provisionally listed, he
3 shall, as soon as practicable after enactment of this Act,
4 afford by public notice a reasonable opportunity to interested
5 persons to submit data relevant thereto. If the data so
6 submitted or otherwise before him do not, in his judgment,
7 establish a reliable basis for including such a color additive
8 or particular use or uses thereof in a list or lists promul-
9 gated under paragraph (1) (A), or for determining the
10 prevailing level or levels of use thereof prior to the enact-
11 ment date with a view to prescribing a temporary tolerance
12 or tolerances for such use or uses under paragraph (1) (C),
13 the Secretary shall establish a temporary tolerance limi-
14 tation at zero level for such use or uses until such time as
15 he finds that it would not be inconsistent with the protection
16 of the public health to increase or dispense with such tem-
17 porary tolerance limitation.

18 EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS

19 INSPECTION ACTS

20 SEC. 204. Nothing in this Act shall be construed to
21 exempt any meat or meat food product or any person from
22 any requirement imposed by or pursuant to the Meat In-

1 spection Act of March 4, 1907 (34 Stat. 1260), as amended
2 or extended (21 U.S.C. 71 and the following), or the
3 Poultry Products Inspection Act (21 U.S.C. 451 and the
4 following).

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

By Mr. HULL and Mr. GOLDWATER

JUNE 17, 1959

Read twice and referred to the Committee on Labor and Public Welfare

AUGUST 21, 1959

Reported with amendments

Senate - Aug. 24, 1959

- 2 -

3. BANKING. Passed without amendment H. R. 8159, to amend the national banking laws to clarify or eliminate ambiguities, repeal obsolete provisions (including provisions for national agricultural credit corporations), etc. This bill will now be sent to the President. pp. 15398-9

Passed as reported H. R. 8160, to liberalize in several respects the limitations on borrowing and lending by national banks (see Digest 124 for a summary of the bill as passed by the House). Sen. Robertson explained that the only amendment of the Senate to the bill "would amend an existing provision which makes the limit on loans to one borrower 25 percent of capital and surplus instead of 10 percent, if the loan is in the form of notes secured by U. S. obligations. The amendment would delete the words 'in the form of notes,' so that obligations secured in this way would have the benefit of the 25 percent figure, instead of the usual 10 percent." pp. 15399-400

4. SCIENCE; RESEARCH. Passed without amendment H. R. 8284, to amend the National Science Foundation Act of 1950 so as to provide increased efficiency of operation and to clarify the Foundations' authority regarding grants, contracts, or fellowships, improved scientific training, etc. (pp. 15384-5) This bill will now be sent to the President. A similar bill, S. 2468, was indefinitely postponed.

5. MINERALS. Passed as reported S. 2181, to amend the Mineral Leasing Act of 1920, so as to modify oil, gas, coal, and certain other mineral leasing requirements and conditions. pp. 15386-8

6. WATER RESOURCES. Passed as reported S. 1257, to grant the consent and approval of Congress to the Wabash Valley Compact. pp. 15388-90

7. COLOR ADDITIVES. Agreed to the committee amendments to S. 2197, to amend the Federal Food, Drug, and Cosmetic Act so as to authorize the use of color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing conditions under which such additives may be safely used (pp. 15394-7). The "Daily Digest" states that the bill was passed as reported. (p. D814).

8. CLAIMS. Passed as reported H. R. 6000, to amend title 28 of the U. S. Code so as to increase the limit for administrative settlement of claims against the U. S. under the tort claims procedure from \$1000 to \$2500 (as passed by the House the limit would have been increased to \$2000). p. 15397

9. INTERGOVERNMENTAL RELATIONS; FREIGHT FORWARDERS. Passed over, at the request of Sen. Keating, H. R. 6904, to establish an Advisory Commission on Intergovernmental Relations (p. 15384) and H. R. 5067, to repeal Sec. 217 of the Merchant Marine Act of 1936, which section has been interpreted by some to mean that Government agencies are still required to use the services of freight forwarders for overseas shipments (p. 15386).

10. CONSERVATION. Sen. Neuberger commended Sen. Murray for his "outstanding leadership" in the field of conservation of natural resources. p. 15407

11. PERSONNEL. Sen. Gruening urged enactment of legislation to provide a health insurance program for retired Federal employees. p. 15376

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF
BUDGET AND FINANCE

(For Department
Staff Only)

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For actions of Aug. 24, 1959
86th-1st, No. 145

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HIGHLIGHTS: Senate passed bill to provide compensation under Soil Bank to producer for actions based on incorrect information; House committee reported similar bill. Sen. Church urged expansion of Public Law 480 program. Rep. McIntire introduced bill to establish revolving fund for REA loans.

SENATE

1. SOIL BANK. Passed without amendment S. 2457, to authorize the Secretary to compensate producers under the Soil Bank for actions based on erroneous information furnished by authorized representatives of the Secretary. p. 15385
2. FARM PROGRAM. Sen. Church criticized the administration's farm program, stated that "flexible price supports, expansion of markets, streamlined administration, freedom to plant, soil bank, and all" has been a "monumental failure", and urged expansion of Public Law 480 programs as a means of disposing of surplus commodities. pp. 15411-4

line, after the word "natural", to strike out "parent" and insert "mother"; in line 8, after the word "beneficiary", to insert "shall not", and at the beginning of line 9, to strike out "shall"; so as to make the bill read:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, for the purposes of sections 101(a) (27) (A) and 205 of the Immigration and Nationality Act, Ourania Ben Blikas shall be held and considered to be the natural-born minor-alien child of Mr. and Mrs. Ben John Blikas, citizens of the United States: Provided, That the natural mother of the beneficiary, shall not, by virtue of such parentage, be accorded any right, privilege, or status under the Immigration and Nationality Act.

The amendments were agreed to.

The bill was ordered to be engrossed for a third reading, read the third time, and passed.

DONALD G. COPLAN

The Senate proceeded to consider the bill (S. 1891) for the relief of Donald G. Coplan, which had been reported from the Committee on the Judiciary, with amendments, on page 1, line 6, after the figure "\$500", to strike out "Such sum represents the amount of the judgment and costs for which the said Donald G. Coplan was held liable to Richard Vossen in a civil action in the courts of the State of Minnesota." and, in lieu thereof, to insert "Such sum represents reimbursement in the amount of the judgment and costs for which the said Donald G. Coplan was held liable and has paid as a result of a civil action in the courts of the State of Minnesota."; on page 2, line 6, after the word "service", to strike out the period and "Such sum shall be paid only on condition that Donald G. Coplan shall use such sum or so much thereof as is necessary to pay such judgment and costs in full", and in line 10, after the word "Act", to strike out "in excess of 10 per centum thereof"; so as to make the bill read:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, the Secretary of the Treasury is authorized and directed to pay, out of any money in the Treasury not otherwise appropriated, to Donald G. Coplan, Minneapolis, Minnesota, the sum of \$500. Such sum represents reimbursement in the amount of the judgment and costs for which the said Donald G. Coplan was held liable and has paid as a result of a civil action in the courts of the State of Minnesota. This civil action arose out of an accident which occurred on October 4, 1955, between an automobile owned by the said Richard Vossen and a United States mail truck driven by the said Donald G. Coplan, a motor vehicle operator in the Minneapolis post office motor vehicle service: Provided, That no part of the amount appropriated in this Act shall be paid to or received by any agent or attorney on account of services rendered in connection with this claim, and the same shall be unlawful, any contract, to the contrary notwithstanding. Any person violating the provisions of this Act shall be deemed guilty of a misdemeanor and upon conviction thereof shall be fined in any sum not exceeding \$1,000.

The amendments were agreed to.

The bill was ordered to be engrossed for a third reading, read the third time, and passed.

JOHN AXEL ARVIDSON

The Senate proceeded to consider the bill (S. 1432) for the relief of John Axel Arvidson, which had been reported from the Committee on the Judiciary, with amendments, in line 3, after the word "of", to strike out "sections 315 and 318" and insert "section 315"; and in line 4, after the word "Act", to insert "or the Act of July 9, 1918,"; so as to make the bill read:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That, notwithstanding the provisions of section 315 of the Immigration and Nationality Act, or the Act of July 9, 1918, John Axel Arvidson shall be held and considered eligible to be naturalized as a citizen of the United States: Provided, That he is otherwise qualified in accordance with the general requirements as to residence, good moral character, attachment to the principles of the Constitution and favorable disposition to the United States as set forth in section 316 of the said Immigration and Nationality Act.

The amendments were agreed to.

The bill was ordered to be engrossed for a third reading, read the third time, and passed.

GRANTING STATUS OF PERMANENT RESIDENCE TO CERTAIN ALIENS

The concurrent resolution (H. Con. Res. 186) favoring the granting of the status of permanent residence to certain aliens was considered and agreed to.

ADMISSION INTO THE UNITED STATES OF CERTAIN ALIENS

The Senate proceeded to consider the joint resolution (H.J. Res. 445) to facilitate the admission into the United States of certain aliens, which had been reported from the Committee on the Judiciary, with an amendment on page 3, after line 12, to insert a new section, as follows:

SEC. 2. For the purposes of the Immigration and Nationality Act, Lee Kuhn Wu and Makoto Yabusaki shall be deemed to be nonquota immigrants.

The amendment was agreed to.

The amendment was ordered to be engrossed, and the joint resolution to be read a third time.

The joint resolution was read the third time, and passed.

VICTOR HOFFER

The bill (H.R. 1595) for the relief of Victor Hoffer was considered, ordered to a third reading, read the third time, and passed.

GANNON BOGGS

The bill (H.R. 2078) for the relief of Gannon Boggs was considered, ordered to a third reading, read the third time, and passed.

ESTATE OF SETH E. LIBBY, JR.

The bill (H.R. 2296) for the relief of the estate of Seth E. Libby, Jr. was considered, ordered to a third reading, read the third time, and passed.

SETTLEMENT OF CLAIMS INCIDENT TO NONCOMBAT ACTIVITIES OF THE COAST GUARD

The bill (H.R. 2741) to amend section 2734 of title 10, United States Code, so as to authorize the Secretary of the Treasury to settle claims arising in foreign countries incident to noncombat activities of the Coast Guard was considered, ordered to a third reading, read the third time, and passed.

AMENDMENT OF TITLE 28, UNITED STATES CODE

The bill (H.R. 2979) to amend section 752 of title 28, United States Code was considered, ordered to a third reading, read the third time, and passed.

EVA MARIE LESHER

The bill (H.R. 4111) for the relief of Eva Marie Leshner was considered, ordered to a third reading, read the third time, and passed.

OMER W. GUAY

The bill (H.R. 5911) for the relief of Omer W. Guay was considered, ordered to a third reading, read the third time, and passed.

COLBERT COLGATE HELD AND CHARLES W. SHELLHORN

The bill (H.R. 6490) for the relief of Colbert Colgate Held and Charles W. Shellhorn was considered, ordered to a third reading, read the third time, and passed.

JOHN B. SUTTER

The bill (H.R. 7085) for the relief of John B. Sutter was considered, ordered to a third reading, read the third time, and passed.

ESTATE OF SAKIHARA KOKI

The bill (H.R. 7638) for the relief of the estate of Sakihara Koki was considered, ordered to a third reading, read the third time, and passed.

RELIEF OF CERTAIN ALIENS

The Senate proceeded to consider the joint resolution (H.J. Res. 444) for the relief of certain aliens which had been reported from the Committee on the Judiciary with amendments, on page 1, at the beginning of line 3 to strike out:

That the Attorney General is authorized and directed to cancel any outstanding orders and warrants of deportation, warrants of arrest, and bonds, which may have issued in the cases of Mrs. Serafina Fernandez, Maldonado, Nicola Perretta, Roberto Garcia Marquez, and Salomon Chehebar. From and after the date of the enactment of this Act, the said persons shall not again be subject to deportation by reason of the same facts upon which such deportation proceedings were commenced or any such warrants and orders have issued: *Provided, That suitable and proper bonds or undertakings, approved by the Attorney General, be deposited as prescribed by section 213 of the said Act.*

On page 2, at the beginning of line 4, to strike out "Sec. 2. For" and insert "That, for"; at the beginning of line 17, to change the section number from "3" to "2"; in line 20, after the name "Roden", to strike out "Ohannes Vartanyan, Agavni Vartanyan,"; on page 3, at the beginning of line 4, to change the section number from "4" to "3"; at the beginning of line 15, to change the section number from "5" to "4"; in line 16, after the word "Act", to strike out "nna Almo,"; in line 20, after the word "fees", to strike out "Provided, That suitable and proper bonds or undertakings, approved by the Attorney General, be deposited as prescribed by section 213 of the said Act in the cases of Anna Almo and Primetta Galli" and insert "Provided, That a suitable and proper bond or undertaking, approved by the Attorney General, be deposited as prescribed by section 213 of the said Act in the case of Primetta Galli,"; on page 4, at the beginning of line 4, to change the section number from "6" to "5"; at the beginning of line 13, to change the section number from "7" to "6"; in line 14, after the word "Act", to strike out "John C. Flores and"; in line 18, after the word "natural", to strike out "parents" and insert "father"; in the same line, after the word "the", where it appears the second time, to strike out "beneficiaries" and insert "beneficiary", and at the beginning of line 22, to strike out "Upon the granting of permanent residence to each alien as provided for in this section of this Act, if such alien was classifiable as a quota immigrant at the time of the enactment of this Act, the Secretary of State shall instruct the proper quota-control officer to reduce by one the quota for the quota area to which the alien is chargeable for the first year that such quota is available."

The amendments were agreed to.

The amendments were ordered to be engrossed, and the joint resolution to be read a third time.

The joint resolution was read the third time and passed.

PROTECTION OF THE PUBLIC HEALTH

The Senate proceeded to consider the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, which has been reported from the Committee on Labor and Public Welfare with amendments on page 6, line 16, in the heading, after the word "Foods", to strike out "Drugs" and insert "Drugs,"; on page 7, line 7 after "(ii)", to strike out ", has" and insert "has,"; on page 8, line 23, after the word "is", to strike out "used," and insert "used,"; on page 9, after line 2, to strike out:

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him established—

(A) that such use, under the condition of use to be specified in the regulations, will be safe;

(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive.

(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive,

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet; and

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data.

And, in lieu thereof, to insert:

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

On page 13, line 24, after the word "health", to insert a colon and "Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.", and on page 15, line 20, after

the word "identification", to strike out "devices," and insert "devices,"; so as to make the bill read:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Color Additive Amendments of 1959".

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Definitions

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or"

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays."

Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

(2) Section 402(c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(1) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

(b) (1) Clause (4) of section 501(a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows: "(4)

if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirement, applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

(c)(1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

Regulations to assure safety of color additives for foods, drugs, and cosmetics

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "Sec. 406." in such section;

(2) repealing section 504;

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or (b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604,"; and (C) inserting the word "or" after "501(b)."

(b) Section 706 of such Act is amended to read as follows:

"Listing and certification of color additives for foods, drugs, and cosmetics"

"When Color Additives Deemed Unsafe"

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

"While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a))."

"Listing of Colors"

"(b)(1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2)(A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are gen-

erally recognized as appropriate for the use of animal experimentation data; and

"(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive."

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors"

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided,* That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations"

"(d) The provisions of section 701(e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations

under subsections (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f) (2); and

"(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

"Fees

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions

"(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

Confidentiality of trade secrets

SEC. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

Changes in cross-references and terminology

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(l) thereof (relating to forgery or unauthorized use of certain identification devices), "404, 406(b), 504, 506, 507, or 604", and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to non-nutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Definitions

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

Effective date

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

Provisional listings of commercially established colors

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional list-

ing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either (A) on the day preceding the enactment date was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene, shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color addi-

tives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) Regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic act, but for the purposes of the application of section 706(e) of the basic act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706.

(B) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706(b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraph (1) (A) and (C) with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1) (A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

Effect on meat inspection and poultry products inspection acts

SEC. 204. Nothing in this act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).

The amendments were agreed to.

Mr. HOLLAND. Mr. President, I support S. 2197, but because of the concern of some persons in my State, at their request I addressed certain questions to Hon. George P. Larrick, Commissioner of Food and Drugs, in the Department of Health, Education, and Welfare, in a letter dated August 20, 1959. I acquainted the chairman of the Committee on Labor and Public Welfare, the distinguished Senator from Alabama [Mr. HILL], with the contents of my letter. I received a written response from Dr. Larrick under the same date, namely August 20, 1959, a copy of which was also furnished to the Senator from Alabama.

I should like to ask the chairman of the committee, who is familiar with both letters, to state whether or not he approves of the positions taken by Dr. Larrick, the Commissioner of Food and Drugs, in his letter of August 20, 1959, replying to my earlier letter of the same date.

Mr. HILL. Mr. President, my views are in accord with the views expressed by Mr. Larrick in his letter to the Senator from Florida [Mr. HOLLAND] dated August 20, 1959.

Mr. HOLLAND. Is my understanding correct that the bill was reported by the unanimous action of the committee headed by the Senator from Alabama, and that the committee, including the chairman, entertain the same views as are expressed in Dr. Larrick's letter?

Mr. HILL. I have not conversed with every one of the 14 members of the committee, but I think I understand the intent and purpose of the bill. I should say that the intent and purpose as supported by the committee are in accord with the views of Dr. Larrick in his letter to the Senator from Florida dated August 20, 1959.

Mr. HOLLAND. I appreciate the reply of the Senator from Alabama.

Mr. President, I ask unanimous consent that my letter to Dr. Larrick and his reply to me, both under date of August 20, 1959, be printed at this point in the RECORD, assuming that that course is agreeable to the Senator from Alabama.

Mr. HILL. It is perfectly agreeable.

There being no objection, the letters were ordered to be printed in the RECORD, as follows:

AUGUST 20, 1959.

HON. GEORGE P. LARRICK,
Commissioner, Food and Drug Administration,
Department of Health, Education,
and Welfare, Washington, D.C.

DEAR MR. LARRICK: Several questions have been raised by our citrus industry with reference to certain provisions of S. 2197, the color additive amendments of 1959. I believe these questions can be cleared up by a

colloquy on the Senate floor if we can agree upon the intent of these provisions in the bill. Therefore, I would like to ask for your comments on three particular matters with the understanding that this letter and your reply thereto will be placed in the CONGRESSIONAL RECORD during debate on the bill as part of the legislative history of the act.

First, the question has been raised as to whether the definition of the term "color additive" as contained in S. 2197 includes the ethylene process now used in the coloring of citrus fruit and certain other fruits and vegetables. In view of the fact that this process does not actually add color, and in view of discussions we have had on the subject, I do not believe there is any intention of covering the ethylene method in this definition. I will appreciate your assurance that this is the case.

Second, the term "promote deception of the consumer" used in the bill is extremely broad. As you know, in the coloring of citrus every effort has been made to prevent the use of color for deception and we would like your assurance that the long established practice of using ethylene and the use of the color recently certified for the coloring of sound, mature citrus fruit meeting the maturity standards of the respective States, are not considered as "promoting deception" as the term is used in the bill. In view of the statements made by the Department in its message transmitting this bill, I feel sure that it is not intended to claim that these processes promote deception, but I would appreciate your confirmation of this conclusion.

Third, it is my understanding that citrus red No. 2 listed under the provisions of Public Law 86-2, 86th Congress, approved March 17, 1959, shall be deemed provisionally listed under the provisions of section 203 of the bill. I will appreciate your confirmation of this conclusion, also.

Thanking you in advance for your cooperation and with kind regards, I remain,

Yours faithfully,

SPESSARD L. HOLLAND.

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington D.C., August 20, 1959.

HON. SPESSARD L. HOLLAND,
U.S. Senate, Washington, D.C.

DEAR SENATOR HOLLAND: This replies to your letter of August 20, 1959, asking for our views on three questions that have been raised about S. 2197, the color additives amendment of 1959.

It is our understanding that the treatment of citrus fruit with ethylene after harvest does not add color, that it suppresses the formation of certain coloring materials, such as chlorophyll and thus allows the yellow or orange coloring contributed by other natural components to become more apparent. Therefore we would not regard ethylene used in this way on citrus fruit as a color additive within the meaning of the bill.

The second question is whether the application of ethylene or of citrus red No. 2 to sound, mature oranges that meet the minimum maturity standards established under the laws of the States in which the oranges are grown would be considered as promoting deception as that term is used in S. 2197. We would not consider such use as promoting deception.

The third question is whether citrus red No. 2 as listed under the provisions of Public Law 86-2 would be deemed provisionally listed under the provisions of section 203 under S. 2197. It would be deemed provisionally listed.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

INCREASE IN LIMIT FOR ADMINISTRATIVE SETTLEMENT OF CLAIMS UNDER THE TORT CLAIMS PROCEDURE

The Senate proceeded to consider the bill (H.R. 6000) to amend title 28 of the United States Code to increase the limit of administrative settlement of claims against the United States under the tort claims procedure to \$3,000, which had been reported from the Committee on the Judiciary with amendments on page 1, line 7, after the word "of", to strike out "\$2,000" and insert "\$2,500"; on page 2, line 2, to strike out "\$2,000" and insert "\$2,500"; in the line after line 5, after the word "of", to strike out "\$2,000" and insert "\$2,500", and in line 9, to strike out "\$2,000" and insert "\$2,500".

The amendments were agreed to.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

The title was amended so as to read: "An act to amend title 28 of the United States Code to increase the limit for administrative settlement of claims against the United States under the tort claims procedure to \$2,500."

BILLS PASSED OVER

The bill (S. 883) to confer jurisdiction upon the U.S. Court of Claims to hear, determine, and render judgment upon claims of customs officers and employees to extra compensation for Sunday, holiday, and overtime services performed after August 31, 1931, and not heretofore paid in accordance with existing law was announced as next in order.

Mr. BARTLETT. Over by request.

The PRESIDING OFFICER. The bill will be passed over.

BILL PASSED TO FOOT OF CALENDAR

The bill (H.R. 3240) for the relief of Mrs. Clare M. Ash was announced as next in order.

Mr. KEATING. Mr. President, I have a request that that bill go over; and pursuant to the request I ask that it go over. But I will not object to its being called up by motion at the end of the call of the calendar.

The PRESIDING OFFICER. The bill will be placed at the foot of the calendar.

BILL PASSED OVER

The bill (S. 2467) to authorize the development of plans and arrangements for the provision of emergency assistance, and the provision of such assistance, to repatriated American nations without available resources, and for other purposes, was announced as next in order.

Mr. BARTLETT. Mr. President, on our side, at least, the report on the bill reached the Calendar Committee only a few minutes before the consideration of

the various bills was begun. We have had no time in which to study the report. Therefore, I ask that the bill go over.

The bill will be passed over.

MRS. CLARE M. ASH

Mr. WILEY. Mr. President, I ask unanimous consent that the Senate proceed at this time to the consideration of Calendar No. 810, House bill 3240, for the relief of Mrs. Clare M. Ash. I have spoken to the Senator who earlier today objected to consideration of the bill during the call of the calendar. He stated he would have no objection to having the bill placed at the foot of the calendar.

Therefore, at this time, I ask unanimous consent for the present consideration of the bill.

The PRESIDING OFFICER. Is there objection?

There being no objection, the bill (H.R. 3240) for the relief of Mrs. Clare M. Ash was considered, ordered to a third reading, read the third time, and passed.

Mr. WILEY. I thank the Senator for his cooperation.

The PRESIDING OFFICER. That completes the call of the calendar.

PAYMENT TO THE GOVERNMENT OF JAPAN

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 639, Senate bill 2130, to authorize a payment to the Government of Japan.

The PRESIDING OFFICER. Is there objection?

There being no objection, the Senate proceeded to the consideration of the bill.

Mr. MANSFIELD. Mr. President, I ask unanimous consent that a statement of the background of the committee action on the bill be printed at this point in the RECORD; and I wish to add that the bill was reported unanimously by the Foreign Relations Committee.

There being no objection, the excerpt from the report (No. 631) was ordered to be printed in the RECORD, as follows:

BACKGROUND AND COMMITTEE ACTION

The Bonin Islands lie about 700 miles due south of Tokyo. During the war, the civilian population of the islands—about 7,000 Japanese nationals—were evacuated by the Japanese Government to the Japanese home islands. Although 135 persons were allowed to return at one point, the United States, since 1945, has repeatedly held that the Bonins should be closed to other settlement for "security reasons."

Article 3 of the Japanese Peace Treaty gives to the United States "the right to exercise all and any powers of administration, legislation, and jurisdiction over the territory and inhabitants of these islands, including their territorial waters."

Unfortunately, the former residents of the Bonins have not been successfully integrated into the Japanese economy, and it is necessary for the Japanese Government to provide them with assistance. Prime Minister Kishi, during his June 1957 visit to Washington, sought relief for the Bonin Islanders, pleading that the problem constituted a definite

irritant in United States-Japanese relations. He favored repatriation and, failing that, indemnification. Subsequently, it was decided that security requirements were such that even limited resettlement was out of the question. The problem then became one of indemnification. The Japanese Government originally requested \$12.5 million, but has agreed to accept \$6 million.

The Department of State and the Department of Defense agree that the former property holders of the Bonins have legitimate claims. The date from which the claims have been calculated is April 28, 1952, which is when the Japanese Peace Treaty took effect. Since the land has not been in use for many years, there was a problem in determining its value. It was decided to measure the claims by the average value of land in the Ryukyu Islands, another group of Japanese islands under U.S. administration. The figure adopted was \$1,060 per acre, and the total value of the land in question was estimated to be \$4 million. Interest at 6 percent per annum (standard for the area) was added to this, raising the total sum to about \$6 million.

Rather than having the U.S. Government adjudicate individual claims, which both State and Defense regard as unwise, it was recommended that the total amount be turned over to the Japanese Government in full satisfaction of the claims.

On July 27, the committee, sitting in executive session, heard testimony in support of the bill from J. Graham Parsons, Assistant Secretary of State for Far Eastern Affairs; and Robert H. Knight, Acting Assistant Secretary of Defense for International and Security Affairs.

The judgment of the U.S. Government is that the overriding consideration in this matter is one of military security. According to Assistant Secretary Knight, "The Department of Defense considers that the unrestricted use of these islands is essential for the security purposes of the United States." The Bonins encompass only 45 square miles, and any resettlement of the area would circumscribe its usefulness as a military site of critical importance.

COMMITTEE RECOMMENDATIONS

The committee agrees that in these special circumstances repatriation of the former residents of the Bonin Islands is not advisable; that in order to avoid a noxious political problem—indeed, a situation that could undermine our position in the Bonin Islands—the proposed \$6 million indemnity should be paid to the Japanese Government. Thus, the committee urges the approval of S. 2130 by the Senate.

Mr. KEATING. Mr. President, will the Senator from Montana yield to me?

The PRESIDING OFFICER (Mr. HARTKE in the chair). Does the Senator from Montana yield to the Senator from New York?

Mr. MANSFIELD. I yield.

Mr. KEATING. I wish to say that this measure is a very important one. I have received authentic information regarding the bill, and that information convinces me of the merit of the bill.

I thank the Senator from Montana.

Mr. MANSFIELD. Mr. President, the bill is a very meritorious one, and its enactment is very much needed at this time. I think it will do much to enhance our good relations with Japan.

The PRESIDING OFFICER. The bill is open to amendment.

If there be no amendment to be proposed, the question is on the engrossment and third reading of the bill.

The bill (S. 2130) was ordered to be engrossed for a third reading, read the third time, and passed, as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That the Secretary of the Treasury is hereby authorized to pay to the Government of Japan a sum of \$6,000,000. The payment of such sum shall constitute full satisfaction and settlement of all claims of Japanese nationals, formerly resident in the Bonin Islands, arising from the use, benefit, or exercise of property rights or interests in the Bonin Islands by the United States for security purposes, for the period beginning April 28, 1952, and continuing until such time as said use, benefit, or exercise is relinquished by the United States.

Sec. 2. There is hereby authorized to be appropriated the sum of \$6,000,000 to carry out the purpose of this Act.

Mr. MANSFIELD. Mr. President, I move that the vote by which Senate bill 2130 was passed be reconsidered.

Mr. JOHNSON of Texas. Mr. President, I move to lay on the table the motion to reconsider.

The motion to lay on the table was agreed to.

AMENDMENT OF NATIONAL BANKING LAWS

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 736, House bill 8159, to amend the national banking laws to clarify or eliminate ambiguities, to repeal certain laws which have become obsolete, and for other purposes.

The PRESIDING OFFICER. Is there objection?

There being no objection, the Senate proceeded to consider the bill.

Mr. GORE. Mr. President—

Mr. JOHNSON of Texas. Mr. President, the Senator from Virginia [Mr. ROBERTSON] has two bills. I was talking to him only a moment ago. The bills are noncontroversial, and both of them were passed unanimously by the House of Representatives; and the Senator from Virginia is anxious to have the Senate act on them today.

After our conversation at the door of the Chamber, apparently the Senator from Virginia left the Chamber, under the impression that the bills would not be brought up by motion.

Mr. President, at this time I suggest the absence of a quorum.

The PRESIDING OFFICER. The clerk will call the roll.

The legislative clerk proceeded to call the roll.

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. GORE obtained the floor.

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the Senator from Tennessee may yield to the Senator from Pennsylvania [Mr. SCOTT] without losing his right to the floor.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JOHNSON of Texas. I thank the Senator from Tennessee for his courtesy.



86TH CONGRESS
1ST SESSION

S. 2197

IN THE HOUSE OF REPRESENTATIVES

AUGUST 25, 1959

Referred to the Committee on Interstate and Foreign Commerce

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

- 1 *Be it enacted by the Senate and House of Representa-*
- 2 *tives of the United States of America in Congress assembled,*
- 3 *That this Act may be cited as the "Color Additive Amend-*
- 4 *ments of 1959".*

1 TITLE I—AMENDMENTS TO THE FEDERAL FOOD,
2 DRUG, AND COSMETIC ACT

3 DEFINITIONS

4 SEC. 101. Section 201, as amended, of the Federal
5 Food, Drug, and Cosmetic Act is further amended as
6 follows:

7 (a) Paragraph (s) of such section (defining the term
8 “food additive”) is amended by redesignating clause (3) as
9 clause (4), and by inserting immediately before clause (4),
10 as so redesignated, the following new clause:

11 “(3) a color additive; or”.

12 (b) Paragraph (t) of such section is redesignated and
13 otherwise amended to read as follows:

14 “(u) The term ‘safe’, as used in paragraph (s) of this
15 section and in sections 409 and 706, has reference to the
16 health of man or animal.”

17 (c) There is inserted, immediately after paragraph (s)
18 of such section, the following new paragraph:

19 “(t) (1) The term ‘color additive’ means a material
20 which—

21 “(A) is a dye, pigment, or other substance made
22 by a process of synthesis or similar artifice, or extracted,
23 isolated, or otherwise derived, with or without inter-

1 mediate or final change of identity, from a vegetable,
2 animal, mineral, or other source, and

3 “(B) when added or applied to a food, drug, or
4 cosmetic, or to the human body or any part thereof, is
5 capable (alone or through reaction with other sub-
6 stance) of imparting color thereto;
7 except that such term does not include any material which
8 the Secretary, by regulation, determines is used (or intended
9 to be used) solely for a purpose or purposes other than color-
10 ing.

11 “(2) The term ‘color’ includes black, white, and inter-
12 mediate grays.”

13 COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE
14 ADULTERATED OR MISBRANDED FOODS, DRUGS, OR COS-
15 METICS

16 Food

17 SEC. 102. (a) (1) Clause (2) (A) of section 402 (a),
18 as amended, of such Act (relating to food deemed adulter-
19 ated by reason of unsafe additives) is further amended by
20 striking out the matter within the parentheses and inserting
21 in lieu thereof the following: “other than one which is (i) a
22 pesticide chemical in or on a raw agricultural commodity;
23 (ii) a food additive; or (iii) a color additive”.

(2) Section 402 (c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

4 “(c) If it is, or it bears or contains, a color additive
5 which is unsafe within the meaning of section 706 (a).”

6 (3) Section 403 of such Act (relating to the circum-
7 stances under which food is deemed misbranded) is amended
8 by adding at the end thereof the following new paragraph:

9 “(1) If it is a color additive, unless its packaging and
10 labeling are in conformity with such packaging and labeling
11 requirements, applicable to such color additive, as may be
12 contained in regulations issued under section 706.”

13 Drugs

(b) (1) Clause (4) of section 501 (a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows: “(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706 (a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706 (a).”

23 (2) Section 502 of such Act (relating to the circum-
24 stances under which drugs are deemed misbranded) is

1 amended by adding at the end thereof the following new
2 paragraph:

3 “(m) If it is a color additive the intended use of which
4 in or on drugs is for the purpose of coloring only, unless its
5 packaging and labeling are in conformity with such packaging
6 and labeling requirements, applicable to such color additive,
7 as may be contained in regulations issued under section 706.”

Cosmetics

9 (c) (1) Section 601(e) of such Act (relating to cos-
10 metics, other than hair dyes, deemed adulterated by reason
11 of uncertified coal-tar color) is amended to read as follows:

12 “(e) If it is not a hair dye and it is, or it bears or
13 contains, a color additive which is unsafe within the meaning
14 of section 706 (a).”

15 (2) Section 602 of such Act (relating to the circum-
16 stances under which cosmetics shall be deemed to be mis-
17 branded) is amended by adding at the end thereof the
18 following new paragraph:

19 “(e) If it is a color additive, unless its packaging and
20 labeling are in conformity with such packaging and labeling
21 requirements, applicable to such color additive, as may be
22 contained in regulations issued under section 706. This
23 paragraph shall not apply to packages of color additives
24 which, with respect to their use for cosmetics, are marketed

1 and intended for use only in or on hair dyes (as defined in
2 the last sentence of section 601 (a)).”

3 REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR
4 FOODS, DRUGS, AND COSMETICS

5 SEC. 103. (a) Such Act is further amended by—

6 (1) repealing subsection (b) of section 406 and
7 striking out the subsection designation “(a)” after
8 “SEC. 406.” in such section;

9 (2) repealing section 504;

10 (3) repealing section 604; and

11 (4) amending section 701 (e) by (A) striking out
12 “406 (a) or (b)” and inserting in lieu thereof “406”;
13 (B) striking out “504, or 604,”; and (C) inserting the
14 word “or” after “501 (b),”.

15 (b) Section 706 of such Act is amended to read as fol-
16 lows:

17 “LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR
18 FOODS, DRUGS, AND COSMETICS

19 “When Color Additives Deemed Unsafe

20 “SEC. 706. (a) A color additive shall, with respect to
21 any particular use (for which it is being used or intended
22 to be used or is represented as suitable) in or on food or
23 drugs or cosmetics, be deemed unsafe for the purposes of the

1 application of section 402 (c), section 501 (a) (4), or
2 section 601 (e), as the case may be, unless—

3 “(1) (A) there is in effect, and such additive and
4 such use are in conformity with, a regulation issued
5 under subsection (b) of this section listing such addi-
6 tive for such use, including any provision of such regula-
7 tion prescribing the conditions under which such addi-
8 tive may be safely used, and (B) such additive either
9 (i) is from a batch certified, in accordance with regu-
10 lations issued pursuant to subsection (c), for such use,
11 or (ii) has, with respect to such use, been exempted
12 by the Secretary from the requirement of certification; or
13 “(2) such additive and such use thereof conform
14 to the terms of an exemption which is in effect pur-
15 suant to subsection (f) of this section.

16 While there are in effect regulations under subsections (b)
17 and (c) of this section relating to a color additive or an
18 exemption pursuant to subsection (f) with respect to such
19 additive, an article shall not, by reason of bearing or con-
20 taining such additive in all respects in accordance with such
21 regulations or such exemption, be considered adulterated
22 within the meaning of clause (1) of section 402 (a) if such
23 article is a food, or within the meaning of section 601 (a)

1 if such article is a cosmetic other than a hair dye (as defined
2 in the last sentence of section 601 (a)).

3 “Listing of Colors

4 “(b) (1) The Secretary shall, by regulation, provide
5 for separately listing color additives for use in or on food,
6 color additives for use in or on drugs, and color additives
7 for use in or on cosmetics, if and to the extent that such
8 additives are suitable and safe for any such use when em-
9 ployed in accordance with such regulations.

10 “(2) (A) Such regulations may list any color additive
11 for use generally in or on food, or in or on drugs, or in or
12 on cosmetics, if the Secretary finds that such additive is
13 suitable and may safely be employed for such general use.

14 “(B) If the data before the Secretary do not establish
15 that the additive satisfies the requirements for listing such
16 additive on the applicable list pursuant to subparagraph
17 (A) of this paragraph, or if the proposal is for listing such
18 additive for a more limited use or uses, such regulations
19 may list such additive only for any more limited use or
20 uses for which it is suitable and may safely be employed.

21 “(3) Such regulations shall, to the extent deemed neces-
22 sary by the Secretary to assure the safety of the use or uses
23 for which a particular color additive is listed, prescribe the
24 conditions under which such additive may be safely em-

1 ployed for such use or uses (including, but not limited to,
2 specifications, hereafter in this section referred to as toler-
3 ance limitations, as to the maximum quantity or quantities
4 which may be used or permitted to remain in or on the article
5 or articles in or on which it is used; specifications as to
6 the manner in which such additive may be added to or used
7 in or on such article or articles; and directions or other label-
8 ing or packaging requirements for such additive).

9 “(4) The Secretary shall not list a color additive under
10 this section for a proposed use unless the data before him
11 establish that such use, under the conditions of use specified
12 in the regulations, will be safe: *Provided, however, That*, a
13 color additive shall be deemed to be suitable and safe for the
14 purpose of listing under this subsection for use generally
15 in or on food, while there is in effect a published finding
16 of the Secretary declaring such substance exempt from the
17 term ‘food additive’ because of its being generally recognized
18 by qualified experts as safe for its intended use, as provided
19 in section 201 (s).

20 “(5) In determining, for the purposes of this section,
21 whether a proposed use of a color additive is safe, the Sec-
22 retary shall consider, among other relevant factors—

23 “(A) the probable consumption of, or other relevant

1 exposure from, the additive and of any substance formed
2 in or on food, drugs, or cosmetics because of the use of
3 the additive;

4 “(B) the cumulative effect, if any, of such additive
5 in the diet of man or animals, taking into account the
6 same or any chemically or pharmacologically related
7 substance or substances in such diet;

8 “(C) safety factors which, in the opinion of ex-
9 perts qualified by scientific training and experience to
10 evaluate the safety of color additives for the use or uses
11 for which the additive is proposed to be listed, are gen-
12 erally recognized as appropriate for the use of animal
13 experimentation data; and

14 “(D) the availability of any needed practicable
15 methods of analysis for determining the identity and
16 quantity of (i) the pure dye and all intermediates and
17 other impurities contained in such color additive, (ii)
18 such additive in or on any article of food, drug, or cos-
19 metic, and (iii) any substance formed in or on such
20 article because of the use of such additive.

21 “(6) The Secretary shall not list a color additive under
22 this subsection for a proposed use if the data before him show
23 that such proposed use would promote deception of the con-
24 sumer in violation of this Act or would otherwise result in

1 misbranding or adulteration within the meaning of this
2 Act.

3 “(7) If, in the judgment of the Secretary, a tolerance
4 limitation is required in order to assure that a proposed use
5 of a color additive will be safe, the Secretary—

6 “(A) shall not list the additive for such use if he
7 finds that the data before him do not establish that such
8 additive, if used within a safe tolerance limitation, would
9 achieve the intended physical or other technical effect;
10 and

11 “(B) shall not fix such tolerance limitation at a
12 level higher than he finds to be reasonably required to
13 accomplish the intended physical or other technical
14 effect.

15 “(8) If, having regard to the aggregate quantity of
16 color additive likely to be consumed in the diet or to be ap-
17 plied to the human body, the Secretary finds that the data
18 before him fail to show that it would be safe and otherwise
19 permissible to list a color additive (or pharmacologically re-
20 lated color additives) for all the uses proposed therefor and
21 at the levels of concentration proposed, the Secretary shall,
22 in determining for which use or uses such additive (or such
23 related additives) shall be or remain listed, or how the
24 aggregate allowable safe tolerance for such additive or addi-

1 tives shall be allocated by him among the uses under con-
2 sideration, take into account, among other relevant factors
3 (and subject to the paramount criterion of safety), (A) the
4 relative marketability of the articles involved as affected by
5 the proposed uses of the color additive (or of such related
6 additives) in or on such articles, and the relative dependence
7 of the industries concerned on such uses; (B) the relative
8 aggregate amounts of such color additive which he estimates
9 would be consumed in the diet or applied to the human body
10 by reason of the various uses and levels of concentration
11 proposed; and (C) the availability, if any, of other color
12 additives suitable and safe for one or more of the uses
13 proposed.

14 "Certification of Colors

15 " (c) The Secretary shall further, by regulation, pro-
16 vide (1) for the certification, with safe diluents or without
17 diluents, of batches of color additives listed pursuant to sub-
18 section (b) and conforming to the requirements for such
19 additives established by regulations under such subsection
20 and this subsection, and (2) for exemption from the require-
21 ment of certification in the case of any such additive, or any
22 listing or use thereof, for which he finds such requirement
23 not to be necessary in the interest of the protection of the
24 public health: *Provided*, That, with respect to any use in
25 or on food for which a listed color additive is deemed to be

1 safe by reason of the proviso to paragraph (4) of subsection
2 (b), the requirement of certification shall be deemed not to
3 be necessary in the interest of public health protection.

4 “Procedure for Issuance, Amendment, or Repeal of
5 Regulations

6 “(d) The provisions of section 701 (e), (f), and (g)
7 of this Act shall apply to and in all respects govern proceed-
8 ings for the issuance, amendment, or repeal of regulations
9 under subsections (b), (c), or (e) of this section (including
10 judicial review of the Secretary’s action in such proceedings)
11 and the admissibility of transcripts of the record of such pro-
12 ceedings in other proceedings, except that—

13 “(1) the Secretary’s order after public hearing
14 (acting upon objections filed to an order made prior to
15 hearing) shall be subject to the requirements of section
16 409 (f) (2) ; and

17 “(2) the scope of judicial review of such order shall
18 be in accordance with the third sentence of paragraph
19 (2), and with the provisions of paragraph (3), of
20 section 409 (g) .

21 “Fees

22 “(e) The admitting to listing and certification of color
23 additives, in accordance with regulations prescribed under
24 this Act, shall be performed only upon payment of such fees,
25 which shall be specified in such regulations, as may be neces-

1 sary to provide, maintain, and equip an adequate service for
2 such purposes.

3 “Exemptions

4 “(f) The Secretary shall by regulation (issued without
5 regard to subsection (d)) provide for exempting from the
6 requirements of this section any color additive or any specific
7 type of use thereof, and any article of food, drug, or cosmetic
8 bearing or containing such additive, intended solely for in-
9 vestigational use by qualified experts when in his opinion
10 such exemption is consistent with the public health.”

11 CONFIDENTIALITY OF TRADE SECRETS

12 SEC. 104. Section 301 (j) , as amended, of such Act,
13 prohibiting disclosure of trade secrets, is amended by strik-
14 ing out “or 704” and inserting in lieu thereof “704, or 706”.

15 CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

16 SEC. 105. Such Act is further amended by—

17 (a) striking out, in section 301 (i) thereof (relat-
18 ing to forgery or unauthorized use of certain identifica-
19 tion devices) , “404, 406 (b) , 504, 506, 507, or 604”,
20 and inserting in lieu thereof “404, 506, 507, or 706”;

21 (b) (1) striking out, in clause (3) of section 303

22 (c) (relating to color manufacturer’s guarantee), the
23 word “coal-tar” wherever it appears in such clause,
24 and (2) inserting after the word “color”, wherever it
25 appears in such clause, the word “additive”; and

(c) striking out "harmless coloring" in section 402 (d) (relating to non-nutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

DEFINITIONS

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

EFFECTIVE DATE

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED COLORS

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to

1 listing of such additives under the basic Act as amended
2 by this Act. A provisional listing (including a deemed
3 provisional listing) of a color additive under this section for
4 any use shall, unless sooner terminated or expiring under
5 the provisions of this section, expire (A) on the closing
6 date (as defined in paragraph (2) of this subsection) or
7 (B) on the effective date of a listing of such additive for
8 such use under section 706 of the basic Act, whichever
9 date first occurs.

10 (2) For the purposes of this section, the term "closing
11 date" means (A) the last day of the two and one-half
12 year period beginning on the enactment date or (B), with
13 respect to a particular provisional listing (or deemed pro-
14 visional listing) of a color additive or use thereof, such later
15 closing date as the Secretary may from time to time establish
16 pursuant to the authority of this paragraph. The Secretary
17 may by regulation, upon application of an interested person
18 or on his own initiative, from time to time postpone the
19 original closing date with respect to a provisional listing (or
20 deemed provisional listing) under this section of a specified
21 color additive, or of a specified use or uses of such additive,
22 for such period or periods as he finds necessary to carry
23 out the purpose of this section, if in the Secretary's judg-
24 ment such action is consistent with the objective of carry-
25 ing to completion in good faith, as soon as reasonably prac-

1 ticable, the scientific investigations necessary for making
2 a determination as to listing such additive, or such specified
3 use or uses thereof, under section 706 of the basic Act. The
4 Secretary may terminate a postponement of the closing
5 date at any time if he finds that such postponement should
6 not have been granted, or that by reason of a change in
7 circumstances the basis for such postponement no longer
8 exists, or that there has been a failure to comply with a
9 requirement for submission of progress reports or with other
10 conditions attached to such postponement.

11 (b) Subject to the other provisions of this section—

12 (1) any color additive which, on the day preceding
13 the enactment date, was listed and certifiable for any
14 use or uses under section 406 (b) , 504, or 604, or under
15 the third proviso of section 402 (c) , of the basic Act,
16 and of which a batch or batches had been certified for
17 such use or uses prior to the enactment date, and

18 (2) any color additive which was commercially
19 used or sold prior to the enactment date for any use or
20 uses in or on any food, drug, or cosmetic, and which
21 either (A) on the day preceding the enactment date
22 was not a material within the purview of any of the pro-
23 visions of the basic Act enumerated in paragraph (1)
24 of this subsection, or (B) is the color additive known
25 as synthetic beta-carotene,

1 shall, beginning on the enactment date, be deemed to be
2 provisionally listed under this section as a color additive for
3 such use or uses.

4 (c) Upon request of any person, the Secretary, by regu-
5 lations issued under subsection (d), shall without delay, if
6 on the basis of the data before him he deems such action con-
7 sistent with the protection of the public health, provisionally
8 list a material as a color additive for any use for which it
9 was listed, and for which a batch or batches of such material
10 had been certified, under section 406 (b), 504, or 604 of
11 the basic Act prior to the enactment date, although such
12 color was no longer listed and certifiable for such use under
13 such sections on the day preceding the enactment date. Such
14 provisional listing shall take effect on the date of publication.

15 (d) (1) The Secretary shall, by regulations issued or
16 amended from time to time under this section—

17 (A) insofar as practicable promulgate and keep
18 current a list or lists of the color additives, and of the
19 particular uses thereof, which he finds are deemed pro-
20 visionally listed under subsection (b), and the presence
21 of a color additive on such a list with respect to a
22 particular use shall, in any proceeding under the basic
23 Act, be conclusive evidence that such provisional listing
24 is in effect:

25 (B) provide for the provisional listing of the color

1 additives and particular uses thereof specified in sub-
2 section (c) ;

3 (C) provide, with respect to particular uses for
4 which color additives are or are deemed to be provision-
5 ally listed, such temporary tolerance limitations (in-
6 cluding such limitations at zero level) and other condi-
7 tions of use and labeling or packaging requirements, if
8 any, as in his judgment are necessary to protect the
9 public health pending listing under section 706 of the
10 basic Act;

11 (D) provide for the certification of batches of such
12 color additives (with or without diluents) for the uses
13 for which they are so listed or deemed to be listed under
14 this section, except that such an additive which is a
15 color additive deemed provisionally listed under sub-
16 section (b) (2) of this section shall be deemed exempt
17 from the requirement of such certification while not sub-
18 ject to a tolerance limitation; and

19 (E) provide for the termination of a provisional
20 listing (or deemed provisional listing) of a color addi-
21 tive or particular use thereof forthwith whenever in his
22 judgment such action is necessary to protect the public
23 health.

24 (2) (A) Regulations under this section shall, from time
25 to time, be issued, amended, or repealed by the Secretary

1 without regard to the requirements of the basic Act, but for
2 the purposes of the application of section 706 (e) of the basic
3 Act (relating to fees) and of determining the availability of
4 appropriations of fees (and of advance deposits to cover
5 fees), proceedings, regulations, and certifications under this
6 section shall be deemed to be proceedings, regulations, and
7 certifications under such section 706.

8 (B) On and after the enactment date, regulations, pro-
9 visional listings, and certifications (or exemptions from cer-
10 tification) in effect under this section shall, for the purpose
11 of determining whether an article is adulterated or mis-
12 branded within the meaning of the basic Act by reason of its
13 being, bearing, or containing a color additive, have the same
14 effect as would regulations, listings, and certifications (or
15 exemptions from certification) under section 706 of the basic
16 Act. A regulation, provisional listing or termination
17 thereof, tolerance limitation, or certification or exemption
18 therefrom, under this section shall not be the basis for any
19 presumption or inference in any proceeding under section
20 706 (b) or (c) of the basic Act.

21 (3) For the purpose of enabling the Secretary to carry
22 out his functions under paragraph (1) (A) and (C) with

1 respect to color additives deemed provisionally listed, he
2 shall, as soon as practicable after enactment of this Act,
3 afford by public notice a reasonable opportunity to interested
4 persons to submit data relevant thereto. If the data so
5 submitted or otherwise before him do not, in his judgment,
6 establish a reliable basis for including such a color additive
7 or particular use or uses thereof in a list or lists promul-
8 gated under paragraph (1) (A), or for determining the
9 prevailing level or levels of use thereof prior to the enact-
10 ment date with a view to prescribing a temporary tolerance
11 or tolerances for such use or uses under paragraph (1) (C),
12 the Secretary shall establish a temporary tolerance limi-
13 tation at zero level for such use or uses until such time as
14 he finds that it would not be inconsistent with the protection
15 of the public health to increase or dispense with such tem-
16 porary tolerance limitation.

17 EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS

18 INSPECTION ACTS

19 SEC. 204. Nothing in this Act shall be construed to
20 exempt any meat or meat food product or any person from
21 any requirement imposed by or pursuant to the Meat In-
22 spection Act of March 4, 1907 (34 Stat. 1260), as amended

1 or extended (21 U.S.C. 71 and the following), or the
2 Poultry Products Inspection Act (21 U.S.C. 451 and the
3 following).

Passed the Senate August 24, 1959.

Attest: FELTON M. JOHNSTON,
Secretary.

AN ACT

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

AUGUST 25, 1959

Referred to the Committee on Interstate and Foreign
Commerce

House - June 2, 1960

H. R. 11394, to amend the Federal Property and Administrative Services Act of 1949 so as to permit donations of surplus property to certain educational institutions.

H. R. 11437, to amend the Federal Property and Administrative Services Act of 1949 so as to permit the donation of foreign excess property to medical institutions, hospitals, clinics, health centers, schools, colleges, and universities.

H. R. 11499, to amend the Federal Property and Administrative Services Act of 1949, as amended, so as to authorize the use of surplus personal property by State distribution agencies.

25. HEALTH; CHEMICAL ADDITIVES. The Interstate and Foreign Commerce Committee voted to report (but did not actually report) the following bills: (p. D495)

~~H. R. 6871, to provide for the extension of traineeship under the Public Health Training Act.~~

~~H. R. 7624, to amend the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.~~

~~S. 1283, to regulate the interstate distribution and sale of packages of hazardous substances intended or suitable for household use.~~

26. WATERSHEDS. The Watershed Development Subcommittee of the Public Works Committee approved watershed projects in Upper Verdigris watershed, Kan., Reelfoot Indian Creek watershed, Tenn. and Ky., and Olmitos and Garcias Creeks watershed, Tex. pp. D495-6

27. INFORMATION; LIBRARIES. The Rules Committee denied granting a rule on H. R. 12125, to amend the Library Services Act in order to extend for 5 years the authorization for appropriations. p. D496

28. LANDS; MINERALS. The Rules Committee denied granting a rule on H. R. 8860, to stabilize the mining of domestic producers of lead and zinc on public, Indian, and other lands. p. D496

ITEMS IN APPENDIX

29. PERSONNEL. Extension of remarks of Rep. Halpern expressing his support of legislation to increase salaries of Federal employees. p. A4687

30. FAS. Extension of remarks of Rep. Natcher congratulating the Foreign Agricultural Service and stating that "the Department of Agriculture is to be commended upon the outstanding work being carried on" by this Service. p. A4689

31. FARM PRODUCTS. Sen. Fulbright commended and inserted an article, "Farm Product Processing: Some New Directions." pp. A4694-6

32. FARM LABOR. Rep. Rogers discussed a visit to Florida by the Senate Subcommittee on Migratory Labor which included field trips to farms and workers' camps, and inserted several articles in support of legislation to improve migratory worker housing. pp. A4709-10

33. FARM PROGRAM. Rep. Kyl inserted a constituent's letter which states that "we need a farm program to give the farmer cost of production plus a reasonable profit, whatever it is -- whether it be subsidy, crop controls, two-price system, or what have you." p. A4713

HOUSE

16. FORESTRY. Passed with amendments H. R. 10572, to authorize and direct that the national forests be managed under principles of multiple use and to produce a sustained yield of products and services (pp. 10856-79). Earlier a Rules Committee resolution for the consideration of this bill was agreed to (pp. 10853-5).

Agreed to the following amendments:

By Rep. Hoffman, Mich., setting out the States rights in jurisdiction over fish and wildlife on national forests (pp. 10875-6).

By Rep. Cooley exempting mineral resources and lands not within national forests from provisions of the bill (pp. 10876-7).

By Rep. Cooley making the establishment and maintenance of wilderness areas consistent with the provisions of the act (p. 10877).

By Rep. Cooley defining the terms "multipleuse" and "sustained yield of the several products and services" (pp. 10877-9).

17. FARM LOANS. Passed with amendments H. R. 11761, to simplify, consolidate, and improve the authority of the Secretary of Agriculture with respect to Farmers Home Administration loans to farmers and ranchers (pp. 10879-91). Earlier a Rules Committee resolution for the consideration of this bill was agreed to (pp. 10855-6). Agreed to an amendment by Rep. Cooley defining, for the purposes of the bill, the term "farm" (p. 10890), and an amendment by Rep. Cooley limiting to 6% per annum the maximum interest rate that can be charged on insured loans (p. 10890).

18. FARM LABOR. The Rules Committee reported a resolution for the consideration of H. R. 12176, to extend the Mexican farm labor program until June 30, 1963. pp. 10907, 10930

19. INDUSTRIAL USES. Conferees were appointed on S. 690, the industrial uses research bill to create an Agricultural Research and Development Commission. Senate conferees have already been appointed. p. 10907

20. SMALL BUSINESS. The Banking and Currency Committee reported with amendment H. R. 11207, to amend the Small Business Act so as to authorize additional loans to small businesses (H. Rept. 1738). p. 10929

21. DEFENSE PRODUCTION. The Banking and Currency Committee reported without amendment H. R. 12052, to extend the Defense Production Act of 1950, as amended, for an additional two years (H. Rept. 1739). p. 10930

22. PERSONNEL. The Education and Labor Committee reported without amendment H. R. 12383, to amend the Federal Employees' Compensation Act to make benefits more realistic in terms of present wage rates (H. Rept. 1743). p. 10930

23. FOREIGN AFFAIRS. The Banking and Currency Committee voted to report (but did not actually report) H. R. 11001, to provide for the participation of the U. S. in the International Development Association. p. D494

24. PROPERTY; EXTENSION WORK. The Donable Property Subcommittee of the Government Operations Committee voted to report to the full committee the following bills: (p. D495)

H. R. 9600, to authorize and direct the transfer of certain personal property to State and county agencies engaged in cooperative agricultural extension work;

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF
BUDGET AND FINANCE

(For Department
Staff Only)

Issued June 8, 1960
For actions of June 7, 1960
36th-2d, No. 103

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HIGHLIGHTS: Sen. Proxmire urged increased price supports for dairy products. Rep. Hoeven introduced sugar bill.

HOUSE - June 7, 1960

1. COLOR ADDITIVES. The Interstate and Foreign Commerce Committee reported with amendment H. R. 7624, to amend the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used (H. Rept. 1761). p. 11193
2. RECLAMATION. Requested the President to return S. 1892, to authorize construction of the Norman, Okla., reclamation project, for a correction in the engrossed copy of the bill. p. 11152
3. WILDLIFE. The Fisheries and Wildlife Subcommittee of the Merchant Marine and Fisheries Committee voted to report to the full committee H. R. 12449, to amend the Migratory Bird Treaty Act to increase the penalties for violation of that Act. The "Daily Digest" states that this bill was amended with instructions to introduce a clean bill. p. D517
4. RECREATION; FLOOD CONTROL. The Flood Control Subcommittee of the Public Works Committee voted to report to the full committee H. R. 900, to provide that 75%

of receipts from certain recreational activities in connection with lands acquired for flood control and other purposes shall be paid to the State.
p. D517

5. IMPORTS. The "Daily Digest" states that conferees agreed to file conference reports on the following bills: p. D517
H. R. 9862, to extend the suspension of the import duty on casein until June 30, 1963;
H. R. 9881, to extend for two years the existing provisions of law relating to the free importation of personal and household effects brought into the U. S. under Government orders;
H. R. 9322, to make permanent the existing suspension of duties on certain coarse wool.
6. FOREIGN AFFAIRS. Rep. Wolf inserted an article describing the work being done by the ICA mission in their programs of community development in rural villages in the Philippines and other underdeveloped areas. pp. 11163-4
7. FOREIGN TRADE. Rep. Morse inserted, and he and several other Representatives criticized, a recent study report on reorganization of the Organization for European Economic Cooperation by calling it an attempt "to circumvent the constitutional provisions which place in the Congress ... the control of the trade policies ..." pp. 11164-85
8. INTEREST RATES. Rep. Patman criticized the administration's interest rate policy which, he stated, will cost the taxpayers \$130,000,000 for refinancing bonds before these bonds mature. pp. 11185
9. PATENTS; RESEARCH. Rep. Holifield discussed his reasons for believing that "the Government ... should own patents resulting from work it has financed" and inserted a statement by Admiral Rickover to back his position. pp. 11185-92

SENATE

10. DAIRY PRICE SUPPORTS. Sen. Proxmire inserted portions of the testimony before the Senate Agriculture and Forestry Committee on S. 2917, to increase dairy price supports, including the testimony of this Department, and stated, "it seems to me these hearings make a devastating case for the bill. It would cost the Federal Government very little. It would significantly increase the depressed income of the dairy farmers of this Nation." pp. 11106-16
11. FOREIGN TRAVEL. Passed as reported S. 3102, to strengthen the domestic and foreign commerce of the U. S. by providing for the establishment of an Office of International Travel and Tourism and a Travel Advisory Board. pp. 11139-45
12. MARINE RESEARCH. The Interstate and Foreign Commerce Committee reported with amendments S. 2692, to provide a ten-year program of oceanographic research and surveys, including research on the utilization of marine products for human consumption, animal feeds, and fertilizers and organic chemicals (S.Rept. 1525). p. 11098
13. WHEAT LOANS. Sen. Morse inserted two letters from Oregon farmers defending the CCC loans they had received on their wheat crops, and Sen. Morse stated the letters "will provide many of the answers to ill-informed persons unfamiliar with the operation and financing of wheat farms." p. 11146

COLOR ADDITIVE AMENDMENTS OF 1960

R E P O R T

OF THE

COMMITTEE ON INTERSTATE AND
FOREIGN COMMERCE
HOUSE OF REPRESENTATIVES

TO ACCOMPANY

H.R. 7624

A BILL TO PROTECT THE PUBLIC HEALTH BY AMENDING THE FEDERAL FOOD, DRUG, AND COSMETIC ACT SO AS TO AUTHORIZE THE USE OF SUITABLE COLOR ADDITIVES IN OR ON FOODS, DRUGS, AND COSMETICS, IN ACCORDANCE WITH REGULATIONS PRESCRIBING THE CONDITIONS (INCLUDING MAXIMUM TOLERANCES) UNDER WHICH SUCH ADDITIVES MAY BE SAFELY USED



JUNE 7, 1960.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

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Union Calendar No. 775

86TH CONGRESS 2d Session	}	HOUSE OF REPRESENTATIVES	}	REPORT No. 1761
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COLOR ADDITIVE AMENDMENTS OF 1960

JUNE 7, 1960.—Committed to the Committee of the Whole House on the State of the Union and ordered to be printed

Mr. HARRIS, from the Committee on Interstate and Foreign Commerce, submitted the following

REPORT

[To accompany H.R. 7624]

The Committee on Interstate and Foreign Commerce, to whom was referred the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, having considered the same, report favorably thereon with amendments and recommend that the bill as amended do pass.

The amendments, as they appear in the reported bill, are as follows:

(1) On page 1, line 4, strike out "1959" and insert in lieu thereof "1960".

(2) On page 3, line 9, strike out the quotation mark, and immediately below line 9, insert the following:

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

(3) On page 9, strike out lines 8 through 21 and insert in lieu thereof the following:

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the

purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

(4) On page 10, line 19, strike out "and".

(5) On page 10, line 25, strike out the period and insert in lieu thereof "; and".

(6) On page 11, immediately above line 8, insert the following:

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

(7) On page 11, lines 10, 12, and 19, immediately after "found" insert "by the Secretary".

(8) On page 11, immediately below line 20, insert the following:

"(C)(i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e)) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary

and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

“(iii) Where—

“(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

“(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

“(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(9) On page 17, line 5, immediately after “health” insert the following:

: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

(10) On page 17, line 13, immediately after "shall" insert the following:

, subject to the provisions of subparagraph (C) of subsection (b)(5) of this section,

(11) On page 17, lines 16 and 17, strike out "subsections (b), (c), or (e)" and insert in lieu thereof "subsection (b) or (c)".

(12) On page 17, immediately below line 20, insert the following:

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b)(5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

(13) On page 19, line 1, strike out "(1)" and insert in lieu thereof "(3)".

(14) On page 19, line 5, strike out "(2)" and insert in lieu thereof "(4)".

(15) On page 25, line 14, strike out "Regulations" and insert in lieu thereof:

Except as provided in subparagraph (C) of this paragraph, regulations

(16) On page 25, line 23, immediately after the period insert the following:

Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such

section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a)(2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(17) On page 28, line 6, strike out “(B)” and insert in lieu thereof “(D)”.

(18) On page 28, line 20, strike out "paragraph (1) (A) and (C)" and insert in lieu thereof "paragraphs (1) (A) and (C) of this subsection".

(19) On page 29, line 15, immediately after "product" insert the following: ", poultry or poultry product,".

PURPOSE OF LEGISLATION

The purpose of this bill is to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations to be issued by the Secretary of Health, Education, and Welfare, prescribing the conditions, including maximum tolerances, under which such additives may be safely used.

GENERAL SUMMARY

The committee bill—

(1) takes "color additives" out of the scope of the Food Additives Amendment of 1958;

(2) repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604);

(3) enacts new, integrated provisions for the separate listing of suitable "color additives," safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted;

(4) provides for the certification (or exemption from certification) of listed color additives for such permitted uses;

(5) adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and

(6) contains transitional provisions for commercially established colors.

HEARINGS

Extensive hearings were held by the committee on this legislation in January, February, March, and May 1960 and a large number of witnesses were heard. The committee also heard from a distinguished group of scientific experts, selected by the President of the National Academy of Sciences, which discussed the scientific problems involved in this legislation, with special emphasis on the Delaney anticancer clause.

BACKGROUND INFORMATION

Under the Federal Food, Drug, and Cosmetic Act the treatment of color additives differs radically as between so-called coal-tar colors and other colors.

1. *Coal-tar colors*.—The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing a coal-tar color is deemed adulterated under section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food and to provide for certifying batches of such colors.

A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504. Section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors.

A cosmetic (other than a hair dye, which is defined to exclude eyelash and eyebrow dyes) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604. Section 604 then directs the Secretary to provide for listing of coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing (*Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958)).

One exception to the prohibition against the listing of a coal-tar color under tolerance limitations was made by the Congress in Public Law 86-2 to permit the temporary listing and certification of the color Citrus Red No. 2 for the coloring of mature oranges under tolerances found to be safe by the Secretary of Health, Education, and Welfare.

2. *Other colors.*—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirements in the case of cosmetics or drugs except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act.

Non-coal-tar coloring materials used in food, when such materials are not generally recognized by experts as safe, are classified as "food additives" under the Food Additives Amendment of 1958 (Public Law 85-929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed to be adulterated if the additive is unsafe within the meaning of section 409. Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being “harmless,” if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the Committee's report:

This Committee feels compelled to indicate that certification of a compound as “harmless and suitable for use” in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (Report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

2. The theoretically “perfect” public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only “harmless” colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called colors on the list may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be com-

pleted—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of non-coal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation (Public Law 86-2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "safe-for-use" principle in the Food Additives Amendment of 1958 (Public Law 85-929). In reporting upon the emergency legislation for citrus red No. 2, this committee said:

It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this is emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic

Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.

It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

EXPLANATION OF COMMITTEE BILL

The committee bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

Major changes proposed

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility.*—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics (other than hair dyes). This would be accomplished by excepting color additives (as defined in the bill) from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it

under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee to Investigate the Use of Chemicals in Foods and Cosmetics, the Delaney committee in the 82d Congress, and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

2. *Safety-of-use principle.*—The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

3. *Delaney anticancer clause.*—One provision of the bill which aroused considerable controversy in the hearings on this legislation is proposed section 706(b)(5)(B) appearing on page 11, line 8, of the reported bill, and often referred to as the Delaney anticancer clause.

This clause provides that a color additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or any part of such additive if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, not involving ingestion, which are considered to be appropriate for the evaluation of the safety of additives for use in food.

This clause also provides that a color additive shall be deemed unsafe and shall not be listed for any use which will not result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of the additive for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

A similar anticancer clause is included in the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act (Public Law 85-929).

There are many unknowns about cancer that are yet to be solved. We do know, however, that today cancer is second only to heart disease as a cause of death among the American people. Every year, approximately 250,000 people die of cancer in this country. Approximately 450,000 new cases of cancer are discovered each year. At any given time about 700,000 persons are under treatment for cancer.

Expert testimony before the committee showed that scientific inquiry into the incidence of cancer among certain occupational groups has been traced, in several instances, to specific substances involved in their environment. Laboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals. It is this fact—namely, that small quantities of certain materials over a period of time will cause abnormal cell growth in animals—that gave rise to the Delaney anticancer clause in the Food Additives Amendment.

The Secretary of Health, Education, and Welfare very strongly urged the retention of the Delaney clause in the reported bill. The reason for his position may be summarized from his statement to the committee as follows:

The preponderance of scientific evidence clearly dictates our position: Our advocacy of the anticancer proviso in the proposed color additives amendment is based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diet of animals. I should like to underline again one statement in particular which I read earlier from the summary of Dr. [G. Burroughs] Mider's review of the role of certain chemical and physical agents in relation to cancer. It is this:

"No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop."

This is why we have no hesitancy in advocating the inclusion of the anticancer clause.

Unless and until there is a sound scientific basis for the establishment of tolerances for carcinogens, I believe the Government has a duty to make clear—in law as well as in administrative policy—that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet.

The population is inadvertently exposed to certain carcinogens. Ultraviolet light occurs in sunlight. The burning of most fuels produces some minute quantities of chemical compounds that elicit cancer in experimental animals, and some of the same agents can be identified in soot, tars, dusts, and similar residues—even from the atmosphere. In view of these facts, it becomes all the more imperative to protect the public from deliberate introduction of additional carcinogenic materials into the human environment.

Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.

Many have oftentimes expressed the fond hope that the day is not far distant when we shall be able to control cancer. A dramatic breakthrough in this sense may never come. Rather, the progress—looked at from the standpoint of reducing the number of cases of cancer—may come only as we are willing to give heed to the kind of leads that are incorporated in the document prepared by Dr. Mider. It is clear that if we include in our diet substances that induce cancer when included in the diet of test animals, we are taking a risk. In the light of the rising number of cases of cancer, why should we take that risk? Why shouldn't the Govern-

ment do everything possible to see to it that we do not involuntarily take that risk?

* * * * *

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

Unless and until cancer research makes a breakthrough at this point, the principle in the anticancer clause is sound. (Statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare, before the House Committee on Interstate and Foreign Commerce, January 26, 1960.)

The Secretary further stated that, even if the Delaney clause is deleted from the bill, he believes that he has the authority to apply the policy that is reflected in that clause but he urged the Congress to join with the executive branch in giving added assurance to the public by including the anticancer clause in the proposed color additives legislation.

The committee heard a large number of witnesses on the anticancer clause, including a distinguished panel of scientific experts on cancer selected by Dr. Detlev W. Bronk, President of the National Academy of Sciences.

One industry witness objected to any anticancer clause. Another witness argued that it is possible to establish safe tolerance levels for substances that produce cancer when fed to test animals. Some would have the ban on cancer producers apply only to colors that induce cancer when ingested in an amount and under conditions reasonably related to their intended use. And another witness proposed that the cancer clause be taken out of its present position in the bill and added with material language changes to section 705(b)(5)(A) so that it would become simply one of the factors for the Secretary to consider in evaluating the safety of a color additive.

It is evident that such proposed changes are intended to give the Secretary the right to establish tolerances for presumed safe levels of colors that produce cancer when tested under appropriate laboratory conditions. Thus, any of the proposals, if adopted, would weaken the present anticancer clause in the reported bill. For this reason all of the proposed changes were rejected by the committee.

The panel discussed in considerable detail the scientific problems that confront us in connection with determination of the cancer-producing potential of chemicals. They pointed out the difficulties of designing and conducting an experiment to determine whether a substance is a cancer producer for man and the difficulties in evaluating the test data after they are obtained.

Some of the panel members have suggested that despite these difficulties, in extraordinary cases, the Secretary of Health, Education, and Welfare should have the authority to decide that a minute amount

of a cancer-producing chemical may be added to man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard.

In commenting on this testimony, the Secretary of Health, Education, and Welfare said:

The Department's position is that the proposed color additives legislation should include an anticancer clause that makes illegal the use of any color that will induce cancer when tested by appropriate methods. We believe this position to be the only sound public policy in view of the fact that our experts tell us present scientific techniques do not permit them to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.

* * * * *

The rallying point against the anticancer provision is the catch phrase that it takes away the scientists's right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for a man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound (statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare before the House Committee on Interstate and Foreign Commerce, May 9, 1960).

In view of the uncertainty surrounding the determination of safe tolerances for carcinogens, the committee decided that the Delaney anticancer provision in the reported bill should be retained without change.

The committee adopted an amendment, discussed below, which provides for an ad hoc advisory committee to study and report on the question of whether a color additive is a carcinogen.

4. *Comprehensive lists.*—The bill retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors “generally recognized” by experts as safe for use. While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—the Secretary of Health, Education, and Welfare does not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color. It may be noted, however, that a committee amendment to the bill deems a color additive to be suitable and safe for the purpose of listing for use generally in food, where there is in effect a published finding of the Department that the substance is generally recognized as safe for its intended use within the meaning of the provisions exempting such substances from the Food Additives Amendments of 1958. ✓

5. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color’s identity. The committee agrees with the Secretary of Health, Education, and Welfare, however, that authority to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

6. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act—i.e., title I of the bill—would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The “commercially established” color additives falling under these transitional provisions are (a) those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill, and (b) those *non*-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero

tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic except that, in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary of Health, Education, and Welfare.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him to do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

7. *Deception*.—A witness before the committee suggested amending proposed section 706(b)(6) to add the word "harmful" before the word "deception" so as to provide that the Secretary shall not list a color additive for a proposed use if the data before him show that such proposed use would "promote harmful deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."

The Federal Food, Drug and Cosmetic Act prohibits, among other things, the introduction of an adulterated or misbranded food, drug, or cosmetic into interstate commerce, or the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce, or while held for sale after interstate shipment. Furthermore, the food additives amendment (sec. 409(c)(3)(B) of the act) specifically prohibits the Secretary from issuing a regulation prescribing the conditions under which a food additive may be safely used if a fair evaluation of the data before him shows that the proposed use of the additive would "promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act."

The committee is of the opinion that it would be unsound policy to legislate against *deception* of the consumer in the food additives law and against *harmful deception* of the consumer in the color additives law. Obviously, the provision against deception of the consumer should be identical under both sections of the law. It should be emphasized that we are dealing here solely with deception which would violate the law. Among the relevant provisions of the Food

and Drug Act aimed at deception are those which deem a food to be adulterated—

(3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is (sec. 402(b)(3) and (4) of the Federal Food, Drug, and Cosmetic Act).

Examples of coloring practices that would promote deception of the consumer in violation of the basic act were cited by the Secretary of Health, Education, and Welfare as follows: (1) the use of artificial color in egg noodles to hide a deficiency in eggs, (2) the use of artificial color on immature apples or oranges to make the fruit appear mature, (3) the use of artificial color in tomato catsup or juice or canned tomatoes prepared from immature raw materials, and (4) the use of artificial color in stale red meat to make it appear fresh.

The Secretary of Health, Education, and Welfare, by letter dated April 21, 1960, has advised the committee that use of artificial coloring, under proper labeling declaration, on mature oranges would not promote deception in violation of the Federal Food, Drug, and Cosmetic Act. Likewise, the Food and Drug Administration, by letter dated June 2, 1960, has advised the committee that the use of safe coloring in oleomargarine or margarine, with appropriate label declaration, or in butter would not promote deception in violation of the act. These letters are included in the appendix to this report.

(8) *Recommended amendments to Food Additives Amendment.*—The Secretary of Health, Education, and Welfare recommended the adoption of two amendments to the Food Additives Amendment of 1958. These proposed amendments are:

(1) A modification of the Delancy anticancer clause to provide that additives used in animal feed which do not adversely affect the animal and which leave no residue either in the animal after slaughter, or in any food product obtained from the living animal, be exempt from the provisions of the clause. The Secretary also suggested a corresponding change with respect to color additives.

(2) A modification of the "prior sanction or approval" (grandfather) clause (sec. 201(s)(3) of the act).

The Secretary's letter of May 13, 1960, submitting these amendments is included in the appendix to this report.

The committee did not consider the above-mentioned amendments because they involved amendments to the food additive amendments which are not directly germane to this bill. They may be considered at a later date.

EXPLANATION OF PRINCIPAL COMMITTEE AMENDMENTS

(1) *Agricultural chemicals affecting color* (p. 3, beginning on line 10 of reported bill)

The committee was advised that certain pesticide chemicals used in fruit production have the effect not only of protecting the trees against plant diseases but also of supporting or otherwise affecting natural plant processes which thus result in the production of better

color and finish in the fruit. Also, some plant growth regulators, when applied to plants, likewise enhance the development of normal color in the produce of such plants. Some fear has been expressed that such chemicals and plant regulators could be considered to fall within the scope of the definition of "color additive" in section 101(c) of the bill since they have the ability to promote the coloring of raw agricultural commodities.

The committee agrees with the Secretary of Health, Education, and Welfare that such chemicals and plant nutrients are not color additives within the meaning of the basic definition of color additive in this bill, since they merely promote the development of the natural color of produce as the result of the normal physiological processes of the plant or produce. To make this clear, however, the committee has inserted an amendment to the effect that the term "color additive" in section 101(c) of the bill shall not be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical which affects the color of fruit or other raw agricultural commodity which is the produce of the soil solely through its effect on plant metabolism or enzymatic processes either before or after harvest. Pesticide chemicals are regulated under section 408 of the Federal Food, Drug, and Cosmetic Act and under the Federal Insecticide, Fungicide, and Rodenticide Act (61 Stat. 163; 7 U.S.C. 135-135k), and there is no necessity for subjecting them to additional regulation under the color additive amendments when their sole effect on color is through such metabolic or enzymatic processes.¹

It is not the intention of the committee, however, to exempt from the provisions of this bill any chemical or nutrient if it also contains a dye, pigment, or other substance whose function is to impart color to the fruit or other raw agricultural commodity.

The views of the Secretary of Health, Education, and Welfare in letters to the committee dated February 8, 1960, and April 21, 1960, and the letter of the Assistant Secretary of Agriculture dated April 14, 1960, expressing their views on this subject, in which the committee concurs, are shown in the appendix to this report.

(2) *Color additives exempted under Food Additives Amendment* (p. 9, beginning on line 8 of reported bill)

This committee amendment revises proposed section 706(b)(4) by transferring the provisions of subparagraphs (B) and (C) thereof, in consolidated and modified form, to proposed section 706(b)(5) (see discussion immediately below) and adding a proviso to the revised section 706(b)(4) providing that a color additive shall be deemed to be suitable and safe for listing for use generally in or on food while there is in effect a published finding by the Secretary declaring that such additive is exempt under the Food Additives Amendment of 1958 because of its being generally recognized by qualified experts as safe for its intended use as provided in section 201(s) of the act.

(3) *Analytical methods for color additives* (p. 11, beginning on line 1 of reported bill)

This committee amendment adds a new subparagraph (iv) to proposed section 706(b)(5)(A) in the bill, which consolidates and modifies the provisions of subparagraphs (B) and (C) of proposed section

¹ Under a recent amendment to the Federal Insecticide, Fungicide, and Rodenticide Act (Public Law 86-139) nematocides, plant regulators, defoliants, and dessicants have been classified as pesticide chemicals.

706(b)(4) in the bill as introduced. These subsections deal with practicable methods of analysis for color additives and for determining the identity and quantity of such additives or their reaction products in foods, drugs, and cosmetics.

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analysis are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe. The committee amendment meets this objection without impairing consumer health protection.

(4) *Ad Hoc Scientific Advisory Committee on Carcinogenicity of Additive* (p. 11, beginning on line 21 of reported bill)

This committee amendment provides that in any proceeding for the issuance, amendment, or repeal of a regulation by the Secretary of Health, Education, and Welfare listing a color additive, any person who will be adversely affected may request that the petition or order thereon or the Secretary's proposal which is the subject of the proceeding be referred to an advisory committee for a report and recommendations with respect to any matter arising under proposed section 706(b)(5)(B) of the bill, commonly referred to as the Delaney anti-cancer clause, if such matter is involved in such proposal or order and requires the exercise of scientific judgment.

Upon such request, the Secretary shall forthwith appoint an advisory committee and shall refer to it for study and for a report and recommendations the question arising under section 706(b)(5)(B). The Secretary may also refer such a matter to such an advisory committee on his own initiative. The petitioner as well as representatives of the Department of Health, Education, and Welfare shall have the right to consult with the advisory committee.

The request for referral, or the Secretary's referral on his own initiative, may be made at any time before, or within 30 days after, publication of the Secretary's order acting upon the petition or proposal.

Within 60 days after the referral date or within an additional 30 days if necessary, the advisory committee shall certify to the Secretary a report and recommendations. Within 30 days after such certification, and after giving due consideration to all the information before him, including the report, the Secretary shall by order confirm or modify any order theretofore issued, or if no such prior order has been issued, he shall by order act upon the petition or other proposal.

Where by reason of section 706(b)(5)(B) the Secretary has initiated a proposal to remove from listing a color additive previously listed and a request has been made for referral of such a proposal to an advisory committee, the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations and he has considered such recommendations unless the Secretary finds that emergency conditions exist necessitating the issuance of an order.

The committee intends by the term "emergency conditions" to mean, in general, a condition which requires immediate action in order to avoid imminent hazard to public health.

The advisory committee shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background. In the unlikely event that the National Academy of Sciences is unable or refuses to act, the Secretary shall select the members of the advisory committee. The size of the committee shall be determined by the Secretary.

Any report, recommendations, underlying data, and reasons certified to the Secretary by such advisory committee shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedures Act (5 U.S.C. 1006(c)) (p. 18, beginning on line 11 of reported bill).

The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing (p. 18, beginning on line 17 of reported bill).

(5) *Color additive deemed to be safe under the proviso in section 706(b)(4) need not be certified* (p. 17, beginning on line 5 of reported bill)

This committee amendment provides that any color additive which has been listed as suitable and safe for use generally in or on food by reason of the proviso in proposed section 706(b)(4), discussed above, need not be certified by the Secretary under proposed section 706(c) in this bill.

(6) *Time schedule governing action on a petition* (p. 17, beginning on line 21 of reported bill)

This committee amendment sets up a time schedule governing the action on a petition to the Secretary for the issuance, amendment, or repeal of a regulation, except where matters are referred to an advisory committee. As stated above, a separate time schedule is prescribed for cases involving advisory committees.

Notice of the proposal made by a petition must be published in general terms by the Secretary within 30 days after filing, and the Secretary's order acting upon such proposal shall be issued within 90 days after the date of the filing of the petition. The Secretary may extend the 90-day period up to but not exceeding 180 days as he deems necessary to enable him to study and investigate this petition. This is the same time schedule as is provided in the Food Additives Amendment of 1958.

- (7) *Review of regulation by Secretary terminating or placing a tolerance limitation on a provisional listing* (p. 26, beginning on line 7 of reported bill)

This committee amendment provides that if the Secretary of Health, Education, and Welfare has, by regulation issued pursuant to the transitional provisions of this legislation, terminated a provisional listing (or deemed provisional listing) of a color additive or a particular use thereof, or if he has established, or made more restrictive, a tolerance limitation or other restriction or requirement with respect to an already effective provisional listing, any person who may be adversely affected by such action may petition the Secretary for an amendment to revoke or modify such action, but such petition will not operate to stay or suspend the effectiveness of such action. The Secretary must afford all interested persons an opportunity to present their views on the proposal of the petition after which the Secretary shall act on the petition by published order.

Any person adversely affected by this order may, within 30 days, file objections thereto, state reasonable grounds therefor, and request a public hearing upon such objections which shall be granted. Based on the evidence adduced at such hearing, the Secretary shall issue an order which may reinstate a terminated provisional listing or alter a previously established temporary tolerance limitation, or alter any other limitation established by him, only if in his judgment the evidence shows that such action will be consistent with the protection of the public health. Such order shall be subject to judicial review in accordance with section 701(f) of the Federal Food, Drug, and Cosmetic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. The court may not stay or suspend the Secretary's order pending conclusion of judicial review.

REPORTS FROM EXECUTIVE DEPARTMENTS AND AGENCIES

The reports from the various executive departments and agencies on H.R. 7624 (S. 2197) are found in the appendix to this report.

The Secretary of Health, Education, and Welfare estimated the cost of enforcing this legislation to be approximately \$1 million during the first year of operation and close to \$900,000 a year thereafter. The details on this estimate are contained in the Secretary's letter of May 29, 1959, reproduced in the appendix to this report.

SECTION-BY-SECTION ANALYSIS OF "COLOR ADDITIVE AMENDMENTS OF 1960"

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act though similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(e) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is

deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are under existing law when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85-929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the above-mentioned changes; and contains transitional provisions for commercially established colors.

II. SECTIONAL ANALYSIS

TITLE I—AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

Section 101

Section 101 amends section 201 (the definitional section) of the basic act as follows:

Section 101(a) of the bill redesignates section 201(s) of the basic act, defining the term "food additive," by excluding color additives from the term "food additive." While coal-tar colors are already, by implication, outside the scope of the operative provisions of the Food Additives Amendment of 1958 (Public Law 85-929), the express exclusion of "color additives" makes clear that, beginning with the date of enactment of this bill, all color additives (as defined in sec. 101(c) of the bill) will fall outside the scope of the provisions on "food additives."

Section 101(b) of the bill redesignates section 201(t) of the basic act as section 201(u) and extends the definition of "safe" to apply to the use of that term in section 706 of the basic act as amended by section 103(b) of the bill.

Section 101(c) of the bill adds to section 201 of the basic act a new subsection (t), which defines the term "color additive" as any dye,

pigment, or other substance, either synthetic or extracted or otherwise derived, which is capable of imparting color to a food, drug, cosmetic, or the human body, but excluding any material that the Secretary, by regulation, determines is used solely for noncoloring purposes. (Black, white, and intermediate grays are expressly included in the term "color.")

As amended by the committee, the definition of "color additive" does not extend to certain pesticide and other agricultural chemicals whose sole effect upon color results from metabolic or enzymatic processes.

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a)(2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges. (See Public Law 86-2.) (Sec. 406(b) of the act would be repealed under another section of the bill.) The effect of these changes would be to (a) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (b) extend them to the color additive itself before being added to food; and (c) use the technique of the pesticide chemicals amendment and food additives amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (l), whereby a food which is a color additive is deemed misbranded unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

Section 102(b)

Paragraph (1) amends section 501(a)(4) of the basic act to deem adulterated any drug containing a color additive solely for purposes of coloring, and any color additive which (with respect to its use in or on drugs) is intended solely for coloring purposes, if these are unsafe within the meaning of section 706(a) of the act. This would replace the present provision of section 501(a)(4), which deems a drug adulterated if it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified under

section 504. (Sec. 504 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 502 of the basic act a new subsection (m) deeming misbranded a drug which is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with packaging and labeling requirements, if any, contained in regulations issued under section 706. (A color additive is, under the definition of "drug" in the basic act, itself a drug when intended for use as a component of drugs.)

Section 102(c)

Paragraph (1) amends section 601(e) of the basic act so as to deem adulterated a cosmetic (other than a hair dye) which is, bears, or contains a color additive which is unsafe within the meaning of section 706 of the act. This would replace the existing provision, which deems adulterated a cosmetic (other than a hair dye) which bears or contains a coal-tar color other than one from a batch certified under section 604. (Sec. 604 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 602 of the act a new subsection (e) so as to deem misbranded a cosmetic which is a color additive (except a color additive for hair dyes) not packaged and labeled in accordance with packaging and labeling requirements, if any, under section 706. (Under the definition of "cosmetic" in the basic act, a color additive which is intended for use as a component of cosmetics is itself considered a cosmetic.)

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C. 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law, sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec. 706 as amended by the bill.) The major provisions of the proposed section 706 are:

Section 706(a)

The basic operative provision of the section, this subsection deems a color additive unsafe for a particular use (or intended use) in or on food, drugs, or cosmetics for the purposes of the application of sections 402(c), 501(a)(4), and 601(e), of the act as amended by the bill, unless the color additive is listed under section 706(b) and complies with the conditions of use prescribed by the regulations listing the additive, and unless the additive is from a batch certified pursuant to regulations under section 706(c) or is exempted from the requirement of such certification. The single exception to these requirements is an exemption, to be provided by regulation (under sec. 706(f)), for color additives intended solely for investigational use by qualified experts.

Where a color additive is used in accordance with the Secretary's regulations, it is also exempted from the general provisions that deem adulterated any food (sec. 402(a)(1)) or cosmetic (sec. 601(a)) bearing or containing a poisonous or deleterious substance that may render it injurious to health. This exempting provision does not apply to hair dye (other than eyebrow and eyelash dye), since coal-tar hair dyes are not covered by section 601(e) of the act.

Section 706(b)

Paragraph (1): The Secretary is required to establish separate lists of color additives for use in respect to food, drugs, and cosmetics, to the extent that the additives are suitable and safe for use when employed in accordance with the regulations listing them.

Paragraph (2): The listing of an additive may be for general use in respect to food, or drugs, or cosmetics, or it may be for a more limited use.

Paragraph (3): The regulations listing the color additive must, to the extent deemed necessary to assure safety of use, prescribe tolerance limitations, other directions relating to the manner of adding or using the additive, labeling or packaging requirements for such additive, and other conditions.

Paragraph (4), as amended by the committee, provides that a color additive may be listed for use only when it is shown that it may be safely used under the conditions prescribed by regulation. While there is in effect a published finding of the Secretary declaring a color additive exempt from the term "food additive" because of being generally recognized by qualified experts as safe, such color additive will be listed for use in foods generally.

Subparagraph (A) of paragraph (5), as amended by the committee, provides that in determining whether a color additive is safe, the Secretary shall consider relevant factors such as probable total consumption and cumulative effect of such additive and related substances, and substances formed when the color is added to a food, drug, or cosmetic and safety factors required in using animal experimentation data, as well as the availability of any needed practicable methods for analysis of the color additive itself and for determining the identity and quantity of the additive and its reaction products in or on foods, drugs, or cosmetics. Such practicable methods of analysis must be available when needed to insure safety and for enforcement of the regulation.

Subparagraph (B) of paragraph (5) provides that a color additive shall be deemed unsafe, and shall not be listed, for any use if the additive is found by the Secretary to induce cancer in man or animal.

Subparagraph (C) of paragraph (5) provides that any person who applies for issuance, amendment, or repeal of a regulation listing a color additive, or who will be adversely affected by such proposal or by any proposed order of the Secretary with respect to a color additive, may request that all scientific questions involving cancer arising under the proposed listing or order shall be referred to an ad hoc advisory committee of qualified experts. The Secretary may also, on his own initiative, refer such matters to an ad hoc committee. The committee, within 60 days (or 90 days if the committee deems the additional time necessary), will report to the Secretary its recommendations.

The report and recommendations of the advisory committee must be considered by the Secretary in passing on the proposal, and become a part of the record of the proceedings with respect to the proposal. Subsequent provisions of the bill require that the Secretary's determinations with respect to proposals involving color additives must be based upon a "fair evaluation of the record."

Where the proposal is one for delisting of a color additive which has been listed under the permanent provisions of the bill, if the matter is referred to an advisory committee, the Secretary may not delist the color until he has received and considered the report and recommendations of the advisory committee, except where emergency conditions exist necessitating the issuance of an order. The committee intends the term "emergency conditions" to mean, in general, a condition which requires immediate action in order to avoid imminent hazard to public health.

Subparagraph (D) of paragraph (5) provides for the composition of advisory committees. The committees will be selected by the National Academy of Sciences from persons qualified as experts in the subject matter of the question referred to the committee and of adequately diversified professional background, and will serve on a temporary basis.

Paragraph (6): The Secretary may not list a color additive for a proposed use if that use would promote deception of the consumer in violation of the act or otherwise result in a misbranding or adulteration within the meaning of the act. (A similar provision is contained in sec. 409(c)(3)(B) of the act, for food additives.)

Paragraph (7): If a tolerance limitation is required to assure safety, a color additive may not be listed unless the data establish that, if used within a safe tolerance, the additive will achieve the intended physical or other technical effect; and the permissible tolerance may be set no higher than the level necessary to accomplish this effect. This requirement is similar to that imposed on the Secretary by section 409(c)(4) of the act with respect to food additives.

Paragraph (8): Where, because of the aggregate quantity of a color additive (or pharmacologically related additives) likely to be involved, the Secretary cannot list the color (or colors) for all proposed uses, he may select among those uses or may apportion the aggregate allowable tolerance among them, subject to the paramount criterion of safety. For the purpose of such selection or allocation, the bill provides for taking into account, among other relevant factors, the marketability of an article as affected by color, and industry dependence on the color uses involved; the quantities of color consumption involved in the various color uses; and the availability of other colors.

Section 706(c)

Directs the Secretary to provide for the certification of batches of color additives and for exemption from the requirement of certification where unnecessary in the interest of the public health. Under this subsection the Secretary could provide for conditioning certification of batches of color additives on the keeping of records of disposal, as he does under existing law. Colors recognized by an effective published finding of the Secretary as exempt from the Food Additives Amendment because generally recognized as safe and listed as safe and suitable for use generally in food pursuant to the proviso in section 706(b)(4) will be exempt from the certification requirement.

Section 706(d)

This subsection, in general, incorporates by reference the procedures of section 701 (e) to (g) which now govern coal-tar colors, except that it adopts the provisions as to "fair evaluation on the basis of the entire record" enacted by the Food Additives Amendment of 1958, and it incorporates certain time limits and provisions for meshing with the ad hoc advisory committee procedure inserted by the committee.¹

Thus, as amended in committee, the procedure governing the issuance, amendment, and repeal of regulations for the listing and certification of color additives would be as follows:

1. A proceeding for the issuance, amendment, or repeal of such a regulation would be begun by a proposal made by the Secretary on his own initiative, or by the filing of a petition by any interested person showing reasonable grounds for the proposal.

2. The Secretary would publish the proposal and afford all interested persons an opportunity to present their views thereon, orally or in writing. If the proceeding is begun by the filing of a petition, notice of the proposal is to be published in general terms within 30 days after such filing.

3. Subsequently, after considering such views, the Secretary must by published order act upon such proposal. If the proceeding is commenced by the filing of a petition, such order of the Secretary, in the absence of prior referral (or request for referral) to an advisory committee, is to be issued within 90 days after filing of the petition, subject to extension for an additional 90 days by the Secretary. (As above stated, under sec. 706(b)(5)(C), special time limits govern in the event of a referral to an ad hoc advisory committee on scientific questions involving cancer.)

4. In the absence of a timely and proper request for hearing, the Secretary's order becomes effective at the time specified therein, but not earlier than the 30th day after publication of the order.

5. Within such 30-day period any person who will be adversely affected by the order if placed in effect may file objections thereto with the Secretary and request a public hearing thereon, and the filing of such objections operates as a stay of those provisions of the order objected to.

6. At the public hearing held on such objections, any report, recommendations, underlying data, and reasons given by an advisory committee to which a matter has been referred under section 706 (b)(5)(C) shall be part of the record if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)). Provision is made for presentation of testimony on behalf of such committee at such hearing with respect to the committee report and recommendations, without precluding any other member of the committee from appearing and testifying.

7. After completion of the hearing, the Secretary shall by published order act upon the objections on which the hearing was held. Such

¹ The committee also added an amendment which deletes a cross-reference in proposed sec. 706(d) in the bill which would have had the effect of providing for hearing and judicial review with respect to regulations establishing fees for the listing and certification of color additives. Under present law as interpreted by the Secretary of Health, Education, and Welfare, the issuance or amendment of regulations establishing schedules of fees for the listing and certification of coal-tar colors is not subject to hearing or judicial review and the Secretary recommends that this policy be continued unchanged. The Secretary is required by proposed sec. 706(e) in the bill to charge fees sufficient to provide, maintain, and equip an adequate service for the listing and certification of color additives.

order would have to be based upon a "fair evaluation of the entire record at such hearing" and set forth in detail the findings and conclusions upon which the order is based. (This requirement is taken from the Food Additives Amendment of 1958 and substituted for the provision in the present coal-tar color procedure that the order be based "only on substantial evidence of such record at such hearing.")

The meaning of the requirement of "fair evaluation of the entire record at such hearing," referred to above and in paragraph 9, below, is explained in this committee's report on the Food Additives Amendment of 1958 (H. Rept. 2284, 85th Cong., pp. 6 and 7).

8. The Secretary's order after hearing would specify the effective date, which must be at least 90 days after publication—

unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

9. A person who will be adversely affected by the Secretary's order if placed in effect may obtain judicial review on the basis of the administrative hearing record by filing a petition with the U.S. court of appeals for the circuit in which such person resides or has his principal place of business. In lieu of the present provision of law as to coal-tar colors which states that the findings of the Secretary as to the facts, if supported by "substantial evidence," shall be conclusive, the bill incorporates the provisions of the Food Additives Amendment of 1958 that the—

findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such [administrative] hearing—

and that the court shall not sustain the Secretary's order if he fails to comply with any of the requirements as to such order summarized under paragraph 7, above.

It should be noted that since proceedings for the issuance, amendment, or repeal of regulations under section 706 (b) or (c) of the bill are rulemaking proceedings, the provision of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006(c)) that "the proponent of a rule * * * shall have the burden of proof" would apply. If the proceeding is initiated by the Secretary in order to remove from a list established under the bill a color additive previously listed, the Secretary would be considered the "proponent" and would thus have the burden of proof to justify the proposed action. The measure of that burden would be to establish that, on the basis of a fair evaluation of all the data, the statutory requirements for the listing of the color additive in question are not, at the time of such proposal, satisfied.

The most important of these requirements is that a color additive shall be listed only if the data before the Secretary establish that the particular use, under the conditions of use specified in the regulations, will be safe. Thus, if in a delisting proceeding the Secretary proves that, on the basis of a fair evaluation of all the data, including such additional data as may be presented by any other party to the proceeding, there is reasonable doubt as to the safety of the color additive for the listed use, the conditions for removal are met.

Section 706(e)

This subsection contains the fee provision (with the reference to coal-tar colors amended to refer to color additives) contained in section 706 under existing law. Under the amended act fees for admitting a color to listing would necessarily include the cost of setting tolerance limitations authorized by section 706(b).

Section 706(f)

The Secretary is required to provide, by regulation not subject to the above-mentioned procedure, for exempting from the operation of section 706 any color additive or use thereof intended solely for investigational use by qualified experts, when such exemption is consistent with the public health. A similar exemption exists in section 409(i) of the act for food additives.

Section 104

Extends section 301(j) of the basic act, which prohibits the revelation and the personal use of trade secrets acquired under the authority of various sections of the act (including sec. 409, relating to food additives), so as to include information obtained under the proposed section 706.

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to, sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (nonnutritive substances in confectionery) of the basic act.

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Section 201

Defines, for the purposes of title II, the term "basic act" as the Federal Food, Drug, and Cosmetic Act; the term "enactment date" as the date of enactment of the bill; and other terms, insofar as also used in the basic act (whether before or after enactment of the bill), as having the same meaning as they have, or had when in effect, under the basic act.

Section 202

Makes the bill effective upon enactment, subject to the transitional provisions of section 203.

Section 203

Subsection (a)(1) declares that this section is intended to make possible, for a reasonable interim period, through provisional listings, the continued use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific tests needed as a basis for making determinations with respect to the definitive listing of such additives under the basic act.

Subsection (a)(1) also directs that a provisional listing (which, while in effect, has the same effect as a listing under sec. 706 of the basic act) shall, if not sooner terminated, expire (i) on the "closing date" or (ii) on the effective date of the additive's listing under section 706, whichever date first occurs.

Subsection (a)(2) defines "closing date" as the last day of the 2½-year period beginning on the enactment date, except that, with respect

to a particular provisional listing, the Secretary could postpone the original closing date for such period or periods as he finds necessary to carry out the declared purpose of this section, if consistent with the objective of completing in good faith, as soon as practicable, the necessary scientific tests needed to make a determination with respect to listing under section 706 of the basic act. Such postponements could be terminated if they should not have been granted or on change of circumstances or on failure to submit required progress reports or meet other conditions.

Subsection (b): First, colors subject to those provisions of present law (secs. 406(b), 504, or 604, or the third proviso to sec. 402(e)) which require the listing and certification of so-called coal-tar colors, are deemed provisionally listed for any use for which they were actually listed under these provisions on the day preceding the enactment date if a batch or batches of the color had been certified prior to that date. Second, a color additive which is either synthetic beta-carotene or which, on the date preceding the enactment date, was not within the purview of the so-called coal-tar color provisions of the law, is deemed provisionally listed under the bill for any use of the color for which it was commercially used or sold prior to the enactment date. (It should be noted that the term "coal-tar color"—which under existing law is interpreted as including synthetic colors which, though not coal-tar derivatives, are so chemically structured as to be capable of being derived from coal tar—is not used in the bill. Synthetic beta-carotene is separately dealt with in the bill because its classification with coal-tar colors under existing law is in dispute and has been the subject of a hearing.)

Subsection (c) requires the Secretary, upon request, to list provisionally any color for any use for which it had been listed, and for which use a batch had actually been certified, under the above-mentioned coal-tar color provisions of existing law prior to the enactment date, although it was not so listed on the day preceding that date, if he deems such action consistent with protection of the public health.

Subsection (d)(1): The Secretary is directed, so far as practicable, (A) to promulgate and maintain current a list of color additives deemed provisionally listed, (B) to provide for provisional listing of color additives upon request in accordance with subsection (c), (C) to prescribe, if needed for public-health protection, temporary tolerance limitations (including zero tolerances) and other conditions of use for color additives provisionally listed, (D) to provide for the certification of batches of provisionally listed color additives (except that a color additive deemed provisionally listed under subsection (b)(2) shall be deemed exempt from certification while not subject to a tolerance); and (E) to provide for the termination of a provisional listing forthwith where necessary to protect the public health.

Section 203(d)(2)(A) of the bill provides, among other things, that proceedings, regulations, and certifications of batches of color, under section 203 (relating to provisional listings of commercially established colors) shall be deemed to be proceedings, regulations, and certifications under section 706 of the basic act (as amended by the bill) for the purpose of the application of the fee provisions (sec. 706(e)) and for the purpose of determining the availability of appropriations of fees (and advance deposits to cover fees). A technical committee amendment adds to this a sentence to the effect that coal-tar color fee

regulations issued prior to enactment of the bill and in effect on the day preceding such enactment shall be deemed to be fee regulations under section 706(e) of the basic act *as amended by the bill*, and that appropriations of fees (and advance deposits) available for the maintenance of the coal-tar color listing and certification service under the law as in effect prior to enactment of the bill shall remain available for the maintenance of the color listing and certification service under section 706 of the basic act as amended by the bill. Such fee regulations, of course, will be subject to further amendment after enactment of the bill.

Subsection (d)(2)(B), which was added by the committee, provides that any person adversely affected by an order terminating a listing of a color additive, or imposing a more restrictive tolerance limitation, under the transitional provisions of the bill may file objections to the order of the Secretary. Subparagraph (C) then provides for public hearings on such objections, and judicial review thereof, in which the findings of the Secretary shall be sustained "only if based upon a fair evaluation of the entire record".

Subsection (d)(2)(D) provides that on and after the enactment date, provisional listing and certification under this section shall have the same effect as listing and certification under section 706 for the purpose of determining whether an article is adulterated or misbranded, but provisional listings and other actions under section 203 of the bill shall not give rise to any presumption or inference in section 706 proceedings.

Subsection (d)(3): In order that the Secretary may be able to promulgate and keep current a list of color additives deemed to be provisionally listed and to prescribe temporary tolerance limitations and other conditions of use with respect to those additives, he is directed to afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data submitted or otherwise before the Secretary do not reliably enable him to include a color in the published list of color additives deemed to be provisionally listed, or to ascertain the levels of use of such an additive prevailing prior to the enactment date, the Secretary is directed to fix a temporary zero tolerance for such colors or uses thereof until he deems a higher tolerance, or the absence of a tolerance limitation, consistent with the public interest.

Section 204

As amended by the committee, this section makes clear that the bill, when enacted, would not relieve any meat or meat food product, poultry or poultry product, or any person from any requirement under the Meat Inspection Act of March 4, 1907, as amended or extended (21 U.S.C. 71 et seq.), or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

CHANGES IN EXISTING LAW

In compliance with clause 3 of rule XIII of the Rules of the House of Representatives, changes in existing law made by the bill, as introduced, are shown as follows (existing law proposed to be omitted is enclosed in black brackets, new matter is printed in italic, existing law in which no change is proposed is shown in roman):

FEDERAL FOOD, DRUG, AND COSMETIC ACT AS AMENDED

CHAPTER I—SHORT TITLE

SECTION 1. This Act may be cited as the Federal Food, Drug, and Cosmetic Act.

CHAPTER II—DEFINITIONS

SEC. 201. For the purposes of this Act—

(a) The term “Territory” means any Territory or possession of the United States, including the District of Columbia and excluding the Canal Zone.

(b) The term “interstate commerce” means (1) commerce between any State or Territory and any place outside thereof, and (2) commerce within the District of Columbia or within any other Territory not organized with a legislative body.

(c) The term “Department” means the U.S. Department of Health, Education, and Welfare.

(d) The term “Secretary” means the Secretary of Health, Education, and Welfare.

(e) The term “person” includes individual, partnership, corporation, and association.

(f) The term “food” means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.

(g) The term “drug” means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any articles specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

(h) The term “device” (except when used in paragraph (n) of this section and in sections 301(i), 403(f), 502(c), and 602(c)) means instruments, apparatus, and contrivances, including their components, parts, and accessories, intended (1) for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; or (2) to affect the structure or any function of the body of man or other animals.

(i) The term "cosmetic" means (1) articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance, and (2) articles intended for use as a component of any such articles; except that such term shall not include soap.

(j) The term "official compendium" means the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, official National Formulary, or any supplement to any of them.

(k) The term "label" means a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this Act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.

(l) The term "immediate container" does not include package liners.

(m) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article.

(n) If an article is alleged to be misbranded because the labeling is misleading, then in determining whether the labeling is misleading there shall be taken into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article to which the labeling relates under the conditions of use prescribed in the labeling thereof or under such conditions of use as are customary or usual.

(o) The representation of a drug, in its labeling, as an antiseptic shall be considered to be a representation that it is a germicide, except in the case of a drug purporting to be, or represented as, an antiseptic for inhibitory use as a wet dressing, ointment, dusting powder, or such other use as involves prolonged contact with the body.

(p) The term "new drug" means—

(1) Any drug the composition of which is such that such drug is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of drugs, as safe for use under the conditions prescribed, recommended, or suggested in the labeling thereof, except that such a drug not so recognized shall not be deemed to be a "new drug" if at any time prior to the enactment of this Act it was subject to the Food and Drugs Act of June 30, 1906, as amended, and if at such time its labeling contained the same representations concerning the conditions of its use; or

(2) Any drug the composition of which is such that such drug, as a result of investigations to determine its safety for use under such conditions, has become so recognized, but which has not, otherwise than in such investigations, been used to a material extent or for a material time under such conditions.

(q) The term "pesticide chemical" means any substance which, alone, in chemical combination or in formulation with one or more other substances, is an "economic poison" within the meaning of the Federal Insecticide, Fungicide, and Rodenticide Act (7 U.S.C., secs. 135-135k) as now in force or as hereafter amended, and which is used in the production, storage, or transportation of raw agricultural commodities.

(r) The term "raw agricultural commodity" means any food in its raw or natural state, including all fruits that are washed, colored, or otherwise treated in their unpeeled natural form prior to marketing.

(s) The term "food additive" means any substance the intended use of which results or may reasonably be expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if such substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use; except that such term does not include—

(1) a pesticide chemical in or on a raw agricultural commodity;

or

(2) a pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity; or

(3) a color additive; or

[(3)] (4) any substance used in accordance with a sanction or approval granted prior to the enactment of this paragraph pursuant to this Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).

(t) (1) The term "color additive" means a material which—

(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

(2) The term "color" includes black, white, and intermediate grays.

[(t)] (u) The term "safe", as used in paragraph (s) of this section and in [section 409] sections 409 and 706, has reference to the health of man or animal.

CHAPTER III—PROHIBITED ACTS AND PENALTIES

PROHIBITED ACTS

SEC. 301. The following acts and the causing thereof are hereby prohibited:

(a) The introduction or delivery for introduction into interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded.

(b) The adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce.

(c) The receipt in interstate commerce of any food, drug, device, or cosmetic that is adulterated or misbranded, and the delivery or proffered delivery thereof for pay or otherwise.

(d) The introduction or delivery for introduction into interstate commerce of any article in violation of section 404 or 505.

(e) The refusal to permit access to or copying of any record as required by section 703.

(f) The refusal to permit entry or inspection as authorized by section 704.

(g) The manufacture within any Territory of any food, drug, device, or cosmetic that is adulterated or misbranded.

(h) The giving of a guaranty or undertaking referred to in section 303(c)(2), which guaranty or undertaking is false, except by a person who relied upon a guaranty or undertaking to the same effect signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the food, drug, device, or cosmetic; or the giving of a guaranty or undertaking referred to in section 303(c)(3), which guaranty or undertaking is false.

(i) Forging, counterfeiting, simulating, or falsely representing, or without proper authority using any mark, stamp, tag, label, or other identification device authorized or required by regulations promulgated under the provisions of section 404, [406(b), 504,] 506, 507, or [604] 706.

(j) The using by any person to his own advantage, or revealing, other than to the Secretary or officers or employees of the Department, or to the courts when relevant in any judicial proceeding under this Act, any information acquired under authority of section 404, 409, 505, 506, 507, [or 704] 704, or 706 concerning any method or process which as a trade secret is entitled to protection.

(k) The alteration, mutilation, destruction, obliteration, or removal of the whole or any part of the labeling of, or the doing of any other act with respect to, a food, drug, device, or cosmetic, if such act is done while such article is held for sale (whether or not the first sale) after shipment in interstate commerce and results in such article being adulterated or misbranded.

(l) The using, on the labeling of any drug or in any advertising relating to such drug, of any representation or suggestion that an application with respect to such drug is effective under section 505, or that such drug complies with the provisions of such section.

(m) The sale or offering for sale of colored oleomargarine or colored margarine, or the possession or serving of colored oleomargarine or colored margarine in violation of section 407(b), or 407(c).

(n) The using, in labeling, advertising or other sales promotion of any reference to any report or analysis furnished in compliance with section 704.

* * * * *

PENALTIES

SEC. 303. (a) Any person who violates any of the provisions of section 301 shall be guilty of a misdemeanor and shall on conviction thereof be subject to imprisonment for not more than one year, or a fine of not more than \$1,000, or both such imprisonment and fine; but if the violation is committed after a conviction of such person under this section has become final such person shall be subject to imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(b) Notwithstanding the provisions of subsection (a) of this section, in case of a violation of any of the provisions of section 301, with intent to defraud or mislead, the penalty shall be imprisonment for not more than three years, or a fine of not more than \$10,000, or both such imprisonment and fine.

(c) No person shall be subject to the penalties of subsection (a) of this section, (1) for having received in interstate commerce any article and delivered it or proffered delivery of it, if such delivery or proffer was made in good faith, unless he refuses to furnish on request of an officer or employee duly designated by the Secretary the name and address of the person from whom he purchased or received such article and copies of all documents, if any there be, pertaining to the delivery of the article to him; or (2) for having violated section 301 (a) or (d), if he establishes a guaranty or undertaking signed by, and containing the name and address of, the person residing in the United States from whom he received in good faith the article, to the effect, in case of an alleged violation of section 301(a), that such article is not adulterated or misbranded, within the meaning of this Act, designating this Act, or to the effect, in case of an alleged violation of section 301(d), that such article is not an article which may not, under the provisions of section 404 or 505, be introduced into interstate commerce; or (3) for having violated section 301(a), where the violation exists because the article is adulterated by reason of containing a **【coal-tar】** color *additive* not from a batch certified in accordance with regulations promulgated by the Secretary under this Act, if such person establishes a guaranty or undertaking signed by, and containing the name and address of, the manufacturer of the **【coal-tar】** color *additive*, to the effect that such color *additive* was from a batch certified in accordance with the applicable regulations promulgated by the Secretary under this Act; or (4) for having violated section 301 (b), (c) or (k) by failure to comply with section 502(f) in respect to an article received in interstate commerce to which neither section 503(a) nor section 503(b)(1) is applicable, if the delivery or proffered delivery was made in good faith and the labeling at the time thereof contained the same directions for use and warning statements as were contained in the labeling at the time of such receipt of such article.

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CHAPTER IV—FOOD

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ADULTERATED FOOD

SEC. 402. A food shall be deemed to be adulterated—

(a)(1) If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance such food shall not be considered adulterated under this clause if the quantity of such substance in such food does not ordinarily render it injurious to health; or (2)(A) if it bears or contains any added poisonous or added deleterious substance, [(except a pesticide chemical in or on a raw agricultural commodity and except a food additive)] (*other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive*) which is unsafe within the meaning of section 406, or (B) if it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of section 408(a); or (C) if it is, or it bears or contains, any food additive which is unsafe within the meaning of section 409: *Provided*, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under section 408 and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed food shall, notwithstanding the provisions of sections 406 and 409, not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed food when ready to eat is not greater than the tolerance prescribed for the raw agricultural commodity; or (3) if it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for food; or (4) if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or (5) if it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter; or (6) if its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 409.

(b)(1) If any valuable constituent has been in whole or in part omitted or abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.

[(c) If it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 406: *Provided*, That this paragraph shall not apply to citrus fruit bearing or containing a coal-tar color if application for listing of such color has been made under this Act and such applica-

tion has not been acted on by the Secretary, if such color was commonly used prior to the enactment of this Act for the purpose of coloring citrus fruit: *Provided further*, That this paragraph shall not apply to oranges meeting minimum maturity standards established by or under the laws of the States in which the oranges were grown and not intended for processing (other than oranges designated by the trade as "packing house elimination"), the skins of which have been colored at any time prior to May 1, 1959, with the coal-tar color certified prior to the enactment of this proviso as F. D. & C. Red 32, or certified after such enactment as External D. & C. Red 14 in accordance with section 21 Code of Federal Regulations, part 9: *And provided further*, That, without regard to the requirements of sections 406(b) and 701(e), the Secretary shall promptly establish, and may from time to time amend, regulations (1) prescribing the conditions (including quantitative tolerance limitations) under which the coal-tar color known as Citrus Red No. 2 (more particularly to be defined in such regulations) may be safely used in coloring the skins of oranges which are not intended or used for processing (or, if so used, are oranges designated in the trade as "packing house elimination"), and which meet minimum maturity standards established by or under the laws of the States in which the oranges are grown, (2) providing for separately listing such color solely for such use on such oranges, and (3) providing for the certification of batches of such color, with or without harmless diluents, for such restricted use; and such oranges, if colored prior to September 1, 1961, and to the enactment by the Congress (subsequent to the date of enactment of this proviso) of general legislation for the listing and certification of food color additives under safe tolerances, in conformity with this proviso and such regulations, with Citrus Red No. 2 from a batch certified in accordance with such regulations, shall not be deemed to be adulterated within the meaning of this paragraph.】

(c) *If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).*

(d) If it is confectionery, and it bears or contains any alcohol or nonnutritive article or substance except 【harmless】 *authorized* coloring, harmless flavoring, harmless resinous glaze not in excess of four-tenths of 1 per centum, natural gum, and pectin: *Provided*, That this paragraph shall not apply to any confectionery by reason of its containing less than one-half of 1 per centum by volume of alcohol derived solely from the use of flavoring extracts, or to any chewing gum by reason of its containing harmless nonnutritive masticatory substances.

(e) If it is oleomargarine or margarine or butter and any of the raw material used therein consisted in whole or in part of any filthy, putrid, or decomposed substance, or such oleomargarine or margarine or butter is otherwise unfit for food.

MISBRANDED FOOD

SEC. 403. A food shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If it is offered for sale under the name of another food.

(c) If it is an imitation of another food, unless its label bears, in type of uniform size and prominence, the word "imitation" and, immediately thereafter, the name of the food imitated.

(d) If its container is so made, formed, or filled as to be misleading.

(e) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(f) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under eustomary conditions of purchase and use.

(g) If it purports to be or is represented as a food for which a definition and standard of identity has been prescribed by regulations as provided by section 401, unless (1) it conforms to such definition and standard, and (2) its label bears the name of the food specified in the definition and standard, and, insofar as may be required by such regulations, the common names of optional ingredients (other than spices, flavoring, and coloring) present in such food.

(h) If it purports to be or is represented as—

(1) a food for which a standard of quality has been prescribed by regulations as provided by section 401, and its quality falls below such standard, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard; or

(2) a food for which a standard or standards of fill of container have been prescribed by regulations as provided by section 401, and it falls below the standard of fill of container applicable thereto, unless its label bears, in such manner and form as such regulations specify, a statement that it falls below such standard.

(i) If it is not subject to the provisions of paragraph (g) of this section unless its label bears (1) the common or usual name of the food, if any there be, and (2) in case it is fabricated from two or more ingredients, the common or usual name of each such ingredient; except that spices, flavorings, and colorings, other than those sold as such, may be designated as spices, flavorings, and colorings without naming each: *Provided*, That, to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, or results in deception or unfair competition, exemptions shall be established by regulations promulgated by the Secretary.

(j) If it purports to be or is represented for special dietary uses, unless its label bears such information concerning its vitamin, mineral, and other dietary properties as the Secretary determines to be, and by regulations prescribes as, necessary in order fully to inform purchasers as to its value for such uses.

(k) If it bears or contains any artificial flavoring, artificial coloring, or chemical preservative, unless it bears labeling stating that fact: *Provided*, That to the extent that compliance with the requirements of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary. The provisions of this paragraph and paragraphs (g) and (i) with respect to artificial coloring shall not apply in the case of butter, cheese, or ice cream.

(l) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.

* * * * *

TOLERANCES FOR POISONOUS INGREDIENTS IN FOOD AND CERTIFICATION OF COAL-TAR COLORS FOR FOOD

SEC. 406. [(a)] Any poisonous or deleterious substance added to any food, except where such substance is required in the production thereof or cannot be avoided by good manufacturing practice shall be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a); but when such substance is so required or cannot be so avoided; the Secretary shall promulgate regulations limiting the quantity therein or thereon to such extent as he finds necessary for the protection of public health, and any quantity exceeding the limits so fixed shall also be deemed to be unsafe for purposes of the application of clause (2)(A) of section 402(a). While such a regulation is in effect limiting the quantity of any such substance in the case of any food, such food shall not, by reason of bearing or containing any added amount of such substance, be considered to be adulterated within the meaning of clause (1) of section 402(a). In determining the quantity of such added substance to be tolerated in or on different articles of food the Secretary shall take into account the extent to which the use of such substance is required or cannot be avoided in the production of each such article, and the other ways in which the consumer may be affected by the same or other poisonous or deleterious substances.

[(b) The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in food and for the certification of batches of such colors, with or without harmless diluents.]

* * * * *

TOLERANCES FOR PESTICIDE CHEMICALS IN OR ON RAW AGRICULTURAL COMMODITIES

SEC. 408. (a) Any poisonous or deleterious pesticide chemical, or any pesticide chemical which is not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, added to a raw agricultural commodity, shall be deemed unsafe for the purposes of the application of clause (2) of section 402(a) unless—

(1) a tolerance for such pesticide chemical in or on the raw agricultural commodity has been prescribed by the Secretary of Health, Education, and Welfare under this section and the quantity of such pesticide chemical in or on the raw agricultural commodity is within the limits of the tolerance so prescribed; or

(2) with respect to use in or on such raw agricultural commodity, the pesticide chemical has been exempted from the requirement of a tolerance by the Secretary under this section.

While a tolerance or exemption from tolerance is in effect for a pesticide chemical with respect to any raw agricultural commodity, such raw agricultural commodity shall not, by reason of bearing or containing

any added amount of such pesticide chemical, be considered to be adulterated within the meaning of clause (1) of section 402(a).

(b) The Secretary shall promulgate regulations establishing tolerances with respect to the use in or on raw agricultural commodities of poisonous or deleterious pesticide chemicals and of pesticide chemicals which are not generally recognized, among experts qualified by scientific training and experience to evaluate the safety of pesticide chemicals, as safe for use, to the extent necessary to protect the public health. In establishing any such regulation, the Secretary shall give appropriate consideration, among other relevant factors, (1) to the necessity for the production of an adequate, wholesome, and economical food supply; (2) to the other ways in which the consumer may be affected by the same pesticide chemical or by other related substances that are poisonous or deleterious; and (3) to the opinion of the Secretary of Agriculture as submitted with a certification of usefulness under subsection (1) of this section. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section. In carrying out the provisions of this section relating to the establishment of tolerances, the Secretary may establish the tolerance applicable with respect to the use of any pesticide chemical in or on any raw agricultural commodity at zero level if the scientific data before the Secretary does not justify the establishment of a greater tolerance.

(c) The Secretary shall promulgate regulations exempting any pesticide chemical from the necessity of a tolerance with respect to use in or on any or all raw agricultural commodities when such a tolerance is not necessary to protect the public health. Such regulations shall be promulgated in the manner prescribed in subsection (d) or (e) of this section.

(d) (1) Any person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act may file with the Secretary of Health, Education, and Welfare, a petition proposing the issuance of a regulation establishing a tolerance for a pesticide chemical which constitutes, or is an ingredient of such economic poison, or exempting the pesticide chemical from the requirement of a tolerance. The petition shall contain data showing—

(A) the name, chemical identity, and composition of the pesticide chemical;

(B) the amount, frequency, and time of application of the pesticide chemical;

(C) full reports of investigations made with respect to the safety of the pesticide chemical;

(D) the results of tests on the amount of residue remaining, including a description of the analytical methods used;

(E) practicable methods for removing residue which exceeds any proposed tolerance;

(F) proposed tolerances for the pesticide chemical if tolerances are proposed; and

(G) reasonable grounds in support of the petition.

Samples of the pesticide chemical shall be furnished to the Secretary upon request. Notice of the filing of such petition shall be published in general terms by the Secretary within thirty days after filing. Such notice shall include the analytical methods available for the de-

termination of the residue of the pesticide chemical for which a tolerance or exemption is proposed.

(2) Within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) with respect to the pesticide chemical named in the petition, the Secretary of Health, Education, and Welfare shall, after giving due consideration to the data submitted in the petition or otherwise before him, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful, or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes, unless within such ninety-day period the person filing the petition requests that the petition be referred to an advisory committee or the Secretary within such period otherwise deems such referral necessary, in either of which events the provisions of paragraph (3) of this subsection shall apply in lieu hereof.

(3) In the event that the person filing the petition requests, within ninety days after a certification of usefulness by the Secretary of Agriculture under subsection (l) with respect to the pesticide chemical named in the petition, that the petition be referred to an advisory committee, or in the event the Secretary of Health, Education, and Welfare within such period otherwise deems such referral necessary, the Secretary of Health, Education, and Welfare shall forthwith submit the petition and other data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal in the petition to the Secretary, together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary shall, after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, by order make public a regulation—

(A) establishing a tolerance for the pesticide chemical named in the petition for the purposes for which it is so certified as useful; or

(B) exempting the pesticide chemical from the necessity of a tolerance for such purposes.

(4) The regulations published under paragraph (2) or (3) of this subsection will be effective upon publication.

(5) Within thirty days after publication, any person adversely affected by a regulation published pursuant to paragraph (2) or (3) of this subsection, or pursuant to subsection (e), may file objections thereto with the Secretary, specifying with particularity the provisions of the regulation deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. A copy of the objections filed by a person other than the petitioner shall

be served on the petitioner, if the regulation was issued pursuant to a petition. The petitioner shall have two weeks to make a written reply to the objections. The Secretary shall thereupon, after due notice, hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. Any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee shall be made a part of the record of the hearing, if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The National Academy of Sciences shall designate a member of the advisory committee to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing: *Provided*, That this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing. As soon as practicable after completion of the hearing, the Secretary shall act upon such objections and by order make public a regulation. Such regulation shall be based only on substantial evidence of record at such hearing, including any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee, and shall set forth detailed findings of fact upon which the regulation is based. No such order shall take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(e) The Secretary may at any time, upon his own initiative or upon the request of any interested person, propose the issuance of a regulation establishing a tolerance for a pesticide chemical or exempting it from the necessity of a tolerance. Thirty days after publication of such a proposal, the Secretary may by order publish a regulation based upon the proposal which shall become effective upon publication unless within such thirty-day period a person who has registered, or who has submitted an application for the registration of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act containing the pesticide chemical named in the proposal, requests that the proposal be referred to an advisory committee. In the event of such a request, the Secretary shall forthwith submit the proposal and other relevant data before him to an advisory committee to be appointed in accordance with subsection (g) of this section. As soon as practicable after such referral, but not later than sixty days thereafter, unless extended as hereinafter provided, the committee shall, after independent study of the data submitted to it by the Secretary and other data before it, certify to the Secretary a report and recommendations on the proposal together with all underlying data and a statement of the reasons or basis for the recommendations. The sixty-day period provided for herein may be extended by the advisory committee for an additional thirty days if the advisory committee deems this necessary. Within thirty days after such certification, the Secretary may, after giving due consideration to all data before him, including such report, recommendations, underlying data and statement, by order publish a regulation establishing a tolerance for the pesticide chemical named in the proposal or exempting it from the necessity of a tolerance which shall become effective upon publica-

tion. Regulations issued under this subsection shall upon publication be subject to paragraph (5) of subsection (d).

(f) All data submitted to the Secretary or to an advisory committee in support of a petition under this section shall be considered confidential by the Secretary and by such advisory committee until publication of a regulation under paragraph (2) or (3) of subsection (d) of this section. Until such publication, such data shall not be revealed to any person other than those authorized by the Secretary or by an advisory committee in the carrying out of their official duties under this section.

(g) Whenever the referral of a petition or proposal to an advisory committee is requested under this section, or the Secretary otherwise deems such referral necessary the Secretary shall forthwith appoint a committee of competent experts to review the petition or proposal and to make a report and recommendations thereon. Each such advisory committee shall be composed of experts, qualified in the subject matter of the petition and of adequately diversified professional background selected by the National Academy of Sciences and shall include one or more representatives from land-grant colleges. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

(h) A person who has filed a petition or who has requested the referral of a proposal to an advisory committee in accordance with the provision of this section, as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with any advisory committee provided for in subsection (g) in connection with the petition or proposal.

(i)(1) In a case of actual controversy as to the validity of any order under subsection (d)(5), (e), or (1) any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within 60 days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) In the case of a petition with respect to an order under subsection (d)(5) or (e), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be

sustained if supported by substantial evidence when considered on the record as a whole, including any report and recommendation of an advisory committee.

(3) In the case of a petition with respect to an order under subsection (1), a copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary of Agriculture, or any officer designated by him for that purpose, and thereupon the Secretary shall file in the court the record of the proceedings on which he based his order, as provided in section 2112 of title 28, United States Code. Upon the filing of such petition, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if supported by substantial evidence when considered on the record as a whole.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below. The Secretary of Health, Education, and Welfare or the Secretary of Agriculture, as the case may be, may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(j) The Secretary may, upon the request of any person who has obtained an experimental permit for a pesticide chemical under the Federal Insecticide, Fungicide, and Rodenticide Act or upon his own initiative, establish a temporary tolerance for the pesticide chemical for the uses covered by the permit whenever in his judgment such action is deemed necessary to protect the public health, or may temporarily exempt such pesticide chemical from a tolerance. In establishing such a tolerance, the Secretary shall give due regard to the necessity for experimental work in developing an adequate, wholesome, and economical food supply and to the limited hazard to the public health involved in such work when conducted in accordance with applicable regulations under the Federal Insecticide, Fungicide, and Rodenticide Act.

(k) Regulations affecting pesticide chemicals in or on raw agricultural commodities which are promulgated under the authority of section 406(a) upon the basis of public hearings instituted before January 1, 1953, in accordance with section 701(e), shall be deemed to be regulations under this section and shall be subject to amendment or repeal as provided in subsection (m).

(l) The Secretary of Agriculture, upon request of any person who has registered, or who has submitted an application for the registra-

tion of, an economic poison under the Federal Insecticide, Fungicide, and Rodenticide Act, and whose request is accompanied by a copy of a petition filed by such person under subsection (d)(1) with respect to a pesticide chemical which constitutes, or is an ingredient of, such economic poison, shall, within thirty days or within sixty days if upon notice prior to the termination of such thirty days the Secretary deems it necessary to postpone action for such period, on the basis of data before him, either—

(1) certify to the Secretary of Health, Education, and Welfare that such pesticide chemical is useful for the purpose for which a tolerance or exemption is sought; or

(2) notify the person requesting the certification of his proposal to certify that the pesticide chemical does not appear to be useful for the purpose for which a tolerance or exemption is sought, or appears to be useful for only some of the purposes for which a tolerance or exemption is sought.

In the event that the Secretary of Agriculture takes the action described in clause (2) of the preceding sentence, the person requesting the certification, within one week after receiving the proposed certification, may either (A) request the Secretary of Agriculture to certify to the Secretary of Health, Education, and Welfare on the basis of the proposed certification; (B) request a hearing on the proposed certification or the parts thereof objected to; or (C) request both such certification and such hearing. If no such action is taken, the Secretary may by order make the certification as proposed. In the event that the action described in clause (A) or (C) is taken, the Secretary shall by order make the certification as proposed with respect to such parts thereof as are requested. In the event a hearing is requested, the Secretary of Agriculture shall provide opportunity for a prompt hearing. The certification of the Secretary of Agriculture as the result of such hearing shall be made by order and shall be based only on substantial evidence of record at the hearing and shall set forth detailed findings of fact. In no event shall the time elapsing between the making of a request for a certification under this subsection and final certification by the Secretary of Agriculture exceed one hundred and sixty days. The Secretary shall submit to the Secretary of Health, Education, and Welfare with any certification of usefulness under this subsection an opinion, based on the data before him, whether the tolerance or exemption proposed by the petitioner reasonably reflects the amount of residue likely to result when the pesticide chemical is used in the manner proposed for the purpose for which the certification is made. The Secretary of Agriculture, after due notice and opportunity for public hearing, is authorized to promulgate rules and regulations for carrying out the provisions of this subsection.

(m) The Secretary of Health, Education, and Welfare shall prescribe by regulations the procedure by which regulations under this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of regulations establishing tolerances, including the appointment of advisory committees and the procedure for referring petitions to such committees.

(n) The provisions of section 303(c) of the Federal Food, Drug, and Cosmetic Act with respect to the furnishing of guaranties shall be applicable to raw agricultural commodities covered by this section.

(o) The Secretary of Health, Education, and Welfare shall by regulation require the payment of such fees as will in the aggregate, in the judgment of the Secretary, be sufficient over a reasonable term to provide, equip, and maintain an adequate service for the performance of the Secretary's functions under this section. Under such regulations, the performance of the Secretary's services or other functions pursuant to this section, including any one or more of the following, may be conditioned upon the payment of such fees: (1) The acceptance of filing of a petition submitted under subsection (d); (2) the promulgation of a regulation establishing a tolerance, or an exemption from the necessity of a tolerance, under this section, or the amendment or repeal of such a regulation; (3) the referral of a petition or proposal under this section to an advisory committee; (4) the acceptance for filing of objections under subsection (d)(5); or (5) the certification and filing in court of a transcript of the proceedings and the record under subsection (i)(2). Such regulations may further provide for waiver or refund of fees in whole or in part when in the judgment of the Secretary such waiver or refund is equitable and not contrary to the purposes of this subsection.

This Act shall take effect upon the date of its enactment [July 22, 1954] except that with respect to pesticide chemicals for which tolerances or exemptions have not been established under section 408 of the Federal Food, Drug, and Cosmetic Act, the amendment to section 402(a) of such Act made by section 2 of this Act shall not be effective—

(1) for the period of one year following the date of the enactment of this Act; or

(2) for such additional period following such period of one year, but not extending beyond two years after the date of the enactment of this Act, as the Secretary of Health, Education, and Welfare may prescribe on the basis of a finding that conditions exist which necessitate the prescribing of such additional period.

FOOD ADDITIVES

UNSAFE FOOD ADDITIVES

SEC. 409. (a) A food additive shall, with respect to any particular use or intended use of such additives, be deemed to be unsafe for the purposes of the application of clause (2)(C) of section 402(a), unless—

(1) it and its use or intended use conform to the terms of an exemption which is in effect pursuant to subsection (i) of this section; or

(2) there is in effect, and it and its use or intended use are in conformity with, a regulation issued under this section prescribing the conditions under which such additive may be safely used.

While such a regulation relating to a food additive is in effect, a food shall not, by reason of bearing or containing such an additive in accordance with the regulation, be considered adulterated within the meaning of clause (1) of section 402(a).

PETITION TO ESTABLISH SAFETY

(b)(1) Any person may, with respect to any intended use of a food additive, file with the Secretary a petition proposing the issuance of a regulation prescribing the conditions under which such additive may be safely used.

(2) Such petition shall, in addition to any explanatory or supporting data, contain—

(A) the name and all pertinent information concerning such food additive, including, where available, its chemical identity and composition;

(B) a statement of the conditions of the proposed use of such additive, including all directions, recommendations, and suggestions proposed for the use of such additive, and including specimens of its proposed labeling;

(C) all relevant data bearing on the physical or other technical effect such additive is intended to produce, and the quantity of such additive required to produce such effect;

(D) a description of practicable methods for determining the quantity of such additive in or on food, and any substance formed in or on food, because of its use; and

(E) full reports of investigations made with respect to the safety for use of such additive, including full information as to the methods and controls used in conducting such investigations.

(3) Upon request of the Secretary, the petitioner shall furnish (or, if the petitioner is not the manufacturer of such additive, the petitioner shall have the manufacturer of such additive furnish, without disclosure to the petitioner) a full description of the methods used in, and the facilities and controls used for, the production of such additive.

(4) Upon request of the Secretary, the petitioner shall furnish samples of the food additive involved, or articles used as components thereof, and of the food in or on which the additive is proposed to be used.

(5) Notice of the regulation proposed by the petitioner shall be published in general terms by the Secretary within thirty days after filing.

ACTION ON THE PETITION

(c)(1) The Secretary shall—

(A) by order establish a regulation (whether or not in accord with that proposed by the petitioner) prescribing, with respect to one or more proposed uses of the food additive involved, the conditions under which such additive may be safely used (including, but not limited to, specifications as to the particular food or classes of food in or on which such additive may be used, the maximum quantity which may be used or permitted to remain in or on such food, the manner in which such additive may be added to or used in or on such food, and any directions or other labeling or packaging requirements for such additive deemed necessary by him to assure the safety of such use), and shall notify the petitioner of such order and the reasons for such action; or

(B) by order deny the petition, and shall notify the petitioner of such order and of the reasons for such action.

(2) The order required by paragraph (1) (A) or (B) of this subsection shall be issued within ninety days after the date of filing of the

petition, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition.

(3) No such regulation shall issue if a fair evaluation of the data before the Secretary—

(A) fails to establish that the proposed use of the food additive, under the conditions of use to be specified in the regulation, will be safe: *Provided*, That no additive shall be deemed to be safe if it is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal; or

(B) shows that the proposed use of the additive would promote deception of the consumer in violation of this Act or would otherwise result in adulteration or in misbranding of food within the meaning of this Act.

(4) If, in the judgment of the Secretary based upon a fair evaluation of the data before him, a tolerance limitation is required in order to assure that the proposed use of an additive will be safe, the Secretary—

(A) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the physical or other technical effect for which such additive is intended; and

(B) shall not establish a regulation for such proposed use if he finds upon a fair evaluation of the data before him that such data do not establish that such use would accomplish the intended physical or other technical effect.

(5) In determining, for the purposes of this section, whether a proposed use of a food additive is safe, the Secretary shall consider among other relevant factors—

(A) the probable consumption of the additive and of any substance formed in or on food because of the use of the additive;

(B) the cumulative effect of such additive in the diet of man or animals, taking into account any chemically or pharmacologically related substance or substances in such diet; and

(C) safety factors which in the opinion of experts qualified by scientific training and experience to evaluate the safety of food additives are generally recognized as appropriate for the use of animal experimentation data.

REGULATION ISSUED ON SECRETARY'S INITIATIVE

(d) The Secretary may at any time, upon his own initiative, propose the issuance of a regulation prescribing, with respect to any particular use of a food additive, the conditions under which such additive may be safely used, and the reasons therefor. After the thirtieth day following publication of such a proposal, the Secretary may by order establish a regulation based upon the proposal.

PUBLICATION AND EFFECTIVE DATE OF ORDERS

(e) Any order, including any regulation established by such order, issued under subsection (c) or (d) of this section, shall be published and shall be effective upon publication, but the Secretary may stay

such effectiveness if, after issuance of such order, a hearing is sought with respect to such order pursuant to subsection (f).

OBJECTIONS AND PUBLIC HEARING

(f)(1) Within thirty days after publication of an order made pursuant to subsection (e) or (d) of this section, any person adversely affected by such an order may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds therefor, and requesting a public hearing upon such objections. The Secretary shall, after due notice, as promptly as possible hold such public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public.

(2) Such order shall be based upon a fair evaluation of the entire record at such hearing, and shall include a statement setting forth in detail the findings and conclusions upon which the order is based.

(3) The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication, unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

JUDICIAL REVIEW

(g)(1) In a case of actual controversy as to the validity of any order issued under subsection (f), including any order thereunder with respect to amendment or repeal of a regulation issued under this section, any person who will be adversely affected by such order may obtain judicial review by filing in the United States Court of Appeals for the circuit wherein such person resides or has his principal place of business, or in the United States Court of Appeals for the District of Columbia Circuit, within sixty days after the entry of such order, a petition praying that the order be set aside in whole or in part.

(2) A copy of such petition shall be forthwith served upon the Secretary, or upon any officer designated by him for that purpose, and thereupon the Secretary shall certify and file in the court a transcript of the proceedings and the record on which he based his order. Upon such filing, the court shall have exclusive jurisdiction to affirm or set aside the order complained of in whole or in part. The findings of the Secretary with respect to questions of fact shall be sustained if based upon a fair evaluation of the entire record at such hearing. The court shall advance on the docket and expedite the disposition of all causes filed therein pursuant to this section.

(3) The court, on such judicial review, shall not sustain the order of the Secretary if he failed to comply with any requirement imposed on him by subsection (f)(2) of this section.

(4) If application is made to the court for leave to adduce additional evidence, the court may order such additional evidence to be taken before the Secretary and to be adduced upon the hearing in such manner and upon such terms and conditions as to the court may seem proper, if such evidence is material and there were reasonable grounds for failure to adduce such evidence in the proceedings below.

The Secretary may modify his findings as to the facts and order by reason of the additional evidence so taken, and shall file with the court such modified findings and order.

(5) The judgment of the court affirming or setting aside, in whole or in part, any order under this section shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in section 1254 of title 28 of the United States Code. The commencement of proceedings under this section shall not, unless specifically ordered by the court to the contrary, operate as a stay of an order.

AMENDMENT OR REPEAL OF REGULATIONS

(h) The Secretary shall by regulation prescribe the procedure by which regulations under the foregoing provisions of this section may be amended or repealed, and such procedure shall conform to the procedure provided in this section for the promulgation of such regulations.

EXEMPTIONS FOR INVESTIGATIONAL USE

(i) Without regard to subsections (b) to (h), inclusive, of this section, the Secretary shall by regulation provide for exempting from the requirements of this section any food additive, and any food bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

CHAPTER V—DRUGS AND DEVICES

ADULTERATED DRUGS AND DEVICES

SEC. 501. A drug or device shall be deemed to be adulterated—

(a)(1) If it consists in whole or in part of any filthy, putrid, or decomposed substance; or (2) if it has been prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or (3) if it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or [(4) if it is a drug and it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 504] (4) *if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).*

(b) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, except that whenever tests or methods of assay have not been prescribed in such compendium, or such tests or methods of assay as are prescribed are, in the judgment of the Secretary, insufficient for the making of such determination, the Secretary shall bring such fact to the attention of the appropriate body charged

with the revision of such compendium, and if such body fails within a reasonable time to prescribe tests or methods of assay which, in the judgment of the Secretary, are sufficient for purposes of this paragraph, then the Secretary shall promulgate regulations prescribing appropriate tests or methods of assay in accordance with which such determination as to strength, quality, or purity shall be made. No drug defined in an official compendium shall be deemed to be adulterated under this paragraph because it differs from the standard of strength, quality, or purity therefor set forth in such compendium, if its difference in strength, quality, or purity from such standards is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homoeopathic drug, in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.

(c) If it is not subject to the provisions of paragraph (b) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.

(d) If it is a drug and any substance has been (1) mixed or packed therewith so as to reduce its quality or strength or (2) substituted wholly or in part therefor.

MISBRANDED DRUGS AND DEVICES

SEC. 502. A drug or device shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in a package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If it is for use by man and contains any quantity of the narcotic or hypnotic substance alpha-eucaine, barbituric acid, beta-eucaine, bromal, cannabis, carbromal, chloral, coca, cocaine, codeine, heroin, marihuana, morphine, opium, paraldehyde, peyote, or sulfonmethane; or any chemical derivative of such substance, which derivative has been by the Secretary, after investigation, found to be, and by regulations designated as, habit forming; unless its label bears the name, and quantity or proportion of such substance or derivative and in juxtaposition therewith the statement "Warning—May be habit forming."

(e) If it is a drug and is not designated solely by a name recognized in an official compendium unless its label bears (1) the common or usual name of the drug, if such there be; and (2), in case it is fabricated from two or more ingredients, the common or usual name of each active

ingredient, including the quantity, kind, and proportion of any alcohol, and also including whether active or not, the name and quantity or proportion of any bromides, ether, chloroform, acetanilid, acetphenetidin, amidopyrine, antipyrine, atropine, hyoscyne, hyoscyamine, arsenic, digitalis, digitalis glucosides, mercury, ouabain, strophanthin, strychnine, thyroid, or any derivative or preparation of any such substances, contained therein: *Provided*, That to the extent that compliance with the requirements of clause (2) of this paragraph is impracticable, exemptions shall be established by regulations promulgated by the Secretary.

(f) Unless its labeling bears (1) adequate directions for use; and (2) such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users: *Provided*, That where any requirement of clause (1) of this paragraph, as applied to any drug or device, is not necessary for the protection of the public health, the Secretary shall promulgate regulations exempting such drug or device from such requirement.

(g) If it purports to be a drug the name of which is recognized in an official compendium, unless it is packaged and labeled as prescribed therein: *Provided*, That the method of packing may be modified with the consent of the Secretary. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homoeopathic Pharmacopoeia of the United States, it shall be subject to the requirements of the United States Pharmacopoeia with respect to packaging and labeling unless it is labeled and offered for sale as a homoeopathic drug in which case it shall be subject to the provisions of the Homoeopathic Pharmacopoeia of the United States, and not to those of the United States Pharmacopoeia.

(h) If it has been found by the Secretary to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Secretary shall by regulations require as necessary for the protection of the public health. No such regulation shall be established for any drug recognized in an official compendium until the Secretary shall have informed the appropriate body charged with the revision of such compendium of the need for such packaging or labeling requirements and such body shall have failed within a reasonable time to prescribe such requirements.

(i)(1) If it is a drug and its container is so made, formed, or filled as to be misleading; or (2) if it is an imitation of another drug; or (3) if it is offered for sale under the name of another drug.

(j) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.

(k) If it is, or purports to be, or is represented as a drug composed wholly or partly of insulin, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 506, and (2) such certificate or release is in effect with respect to such drug.

(l) If it is, or purports to be, or is represented as a drug composed wholly or partly of any kind of penicillin, streptomycin, chlortetracycline, chloramphenicol, or bacitracin, or any derivative thereof, unless (1) it is from a batch with respect to which a certificate or release has been issued pursuant to section 507, and (2) such certificate

or release is in effect with respect to such drug: *Provided*, That this paragraph shall not apply to any drug or class of drugs exempted by regulations promulgated under section 507 (c) or (d).

(m) *If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.*

* * * * *

[CERTIFICATION OF COAL-TAR COLORS FOR DRUGS

[SEC. 504. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in drugs for purposes of coloring only and for the certification of batches of such colors, with or without harmless diluents.]

* * * * *

CHAPTER VI—COSMETICS

ADULTERATED COSMETICS

SEC. 601. A cosmetic shall be deemed to be adulterated—

(a) If it bears or contains any poisonous or deleterious substance which may render it injurious to users under the conditions of use prescribed in the labeling thereof, or under such conditions of use as are customary or usual: *Provided*, That this provision shall not apply to coal-tar hair dye, the label of which bears the following legend conspicuously displayed thereon: "Caution—This product contains ingredients which may cause skin irritation on certain individuals and a preliminary test according to accompanying directions should first be made. This product must not be used for dyeing the eyelashes or eyebrows; to do so may cause blindness.", and the labeling of which bears adequate directions for such preliminary testing. For the purposes of this paragraph and paragraph (e) the term "hair dye" shall not include eyelash dyes or eyebrow dyes.

(b) If it consists in whole or in part of any filthy, putrid, or decomposed substance.

(c) If it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

(d) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health.

[(e) If it is not a hair dye and it bears or contains a coal-tar color other than one from a batch that has been certified in accordance with regulations as provided by section 604.]

(e) *If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).*

MISBRANDED COSMETICS

SEC. 602. A cosmetic shall be deemed to be misbranded—

(a) If its labeling is false or misleading in any particular.

(b) If in package form unless it bears a label containing (1) the name and place of business of the manufacturer, packer, or distributor; and (2) an accurate statement of the quantity of the contents in terms of weight, measure, or numerical count: *Provided*, That under clause (2) of this paragraph reasonable variations shall be permitted, and exemptions as to small packages shall be established, by regulations prescribed by the Secretary.

(c) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

(d) If its container is so made, formed, or filled as to be misleading.

(e) *If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).*

* * * * *

[CERTIFICATION OF COAL-TAR COLORS FOR COSMETICS

[SEC. 604. The Secretary shall promulgate regulations providing for the listing of coal-tar colors which are harmless and suitable for use in cosmetics and for the certification of batches of such colors, with or without harmless diluents.]

CHAPTER VII—GENERAL ADMINISTRATIVE PROVISIONS

REGULATIONS AND HEARINGS

SEC. 701. (a) The authority to promulgate regulations for the efficient enforcement of this Act, except as otherwise provided in this section, is hereby vested in the Secretary.

(b) The Secretary of the Treasury and the Secretary of Health, Education, and Welfare shall jointly prescribe regulations for the efficient enforcement of the provisions of section 801, except as otherwise provided therein. Such regulations shall be promulgated in such manner and take effect at such time, after due notice, as the Secretary of Health, Education, and Welfare shall determine.

(c) Hearings authorized or required by this Act shall be conducted by the Secretary or such officer or employee as he may designate for the purpose.

(d) The definitions and standards of identity promulgated in accordance with the provisions of this Act shall be effective for the purposes of the enforcement of this Act; notwithstanding such definitions and standards as may be contained in other laws of the United States and regulations promulgated thereunder.

(e)(1) Any action for the issuance, amendment, or repeal of any regulation under section 401, 403(j), 404(a), 406 [(a) or (b)], 501(b), or 502 (d) or (h), [504, or 604,] of this Act shall be begun by a proposal made (A) by the Secretary on his own initiative, or (B) by petition of any interested person, showing reasonable grounds therefor, filed with the Secretary. The Secretary shall publish such proposal and shall afford all interested persons an opportunity to present their views thereon, orally or in writing. As soon as practicable thereafter, the Secretary shall by order act upon such proposal and shall make such order public. Except as provided in paragraph (2), the order shall become effective at such time as may be specified therein but not prior to the day following the last day on which objections may be filed under such paragraph.

(2) On or before the thirtieth day after the date on which an order entered under paragraph (1) is made public, any person who will be adversely affected by such order if placed in effect may file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating the grounds therefor, and requesting a public hearing upon such objections. Until final action upon such objections is taken by the Secretary under paragraph (3), the filing of such objections shall operate to stay the effectiveness of those provisions of the order to which the objections are made. As soon as practicable after the time for filing objections has expired the Secretary shall publish a notice in the Federal Register specifying those parts of the order which have been stayed by the filing of objections and, if no objections have been filed, stating that fact.

(3) As soon as practicable after such request for a public hearing, the Secretary, after due notice, shall hold such a public hearing for the purpose of receiving evidence relevant and material to the issues raised by such objections. At the hearing, any interested person may be heard in person or by representative. As soon as practicable after completion of the hearing, the Secretary shall by order act upon such objections and make such order public. Such order shall be based only on substantial evidence of record at such hearing and shall set forth, as part of the order, detailed findings of fact on which the order is based. The Secretary shall specify in the order the date on which it shall take effect, except that it shall not be made to take effect prior to the ninetieth day after its publication unless the Secretary finds that emergency conditions exist necessitating an earlier effective date, in which event the Secretary shall specify in the order his findings as to such conditions.

(f)(1) In a case of actual controversy as to the validity of any order under subsection (e), any person who will be adversely affected by such order if placed in effect may at any time prior to the ninetieth day after such order is issued file a petition with the Circuit Court of Appeals of the United States for the circuit wherein such person resides or has his principal place of business, for a judicial review of such order. A copy of the petition shall be forthwith transmitted by the clerk of the court to the Secretary or other officer designated by him for that purpose. The Secretary thereupon shall file in the court the record of the proceedings on which the Secretary based his order, as provided in section 2112 of title 28, United States Code.

(2) If the petitioner applies to the court for leave to adduce additional evidence, and shows to the satisfaction of the court that such additional evidence is material and that there were reasonable grounds for the failure to adduce such evidence in the proceeding before the Secretary, the court may order such additional evidence (and evidence in rebuttal thereof) to be taken before the Secretary, and to be adduced upon the hearing, in such manner and upon such terms and conditions as to the court may seem proper. The Secretary may modify his findings as to the facts, or make new findings, by reason of the additional evidence so taken, and he shall file such modified or new findings, and his recommendation, if any, for the modification or setting aside of his original order, with the return of such additional evidence.

(3) Upon the filing of the petition referred to in paragraph (1) of this subsection, the court shall have jurisdiction to affirm the order, or to set it aside in whole or in part, temporarily or permanently. If the order of the Secretary refuses to issue, amend, or repeal a regulation and such order is not in accordance with law the court shall by its judgment order the Secretary to take action with respect to such regulation, in accordance with law. The findings of the Secretary as to the facts, if supported by substantial evidence, shall be conclusive [now covered by U.S.C. title 28, sec. 1254].

(4) The judgment of the court affirming or setting aside, in whole or in part, any such order of the Secretary shall be final, subject to review by the Supreme Court of the United States upon certiorari or certification as provided in sections 239 and 240 of the Judicial Code, as amended.

(5) Any action instituted under this subsection shall survive notwithstanding any change in the person occupying the office of Secretary or any vacancy in such office.

(6) The remedies provided for in this subsection shall be in addition to and not in substitution for any other remedies provided by law.

(g) A certified copy of the transcript of the record and proceedings under subsection (e) shall be furnished by the Secretary to any interested party at his request, and payment of the costs thereof, and shall be admissible in any criminal, libel for condemnation, exclusion of imports, or other proceeding arising under or in respect to this Act, irrespective of whether proceedings with respect to the order have previously been instituted or become final under subsection (f).

* * * * *

[COST OF CERTIFICATION OF COAL-TAR COLORS

[SEC. 706. The admitting to listing and certification of coal-tar colors, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.]

LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS,
AND COSMETICS*When Color Additives Deemed Unsafe*

SEC. 706. (a) *A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—*

(1)(A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

Listing of Colors

(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used

in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish—

(A) that such use, under the conditions of use to be specified in the regulations, will be safe;

(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive.

(5)(A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive,

(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet; and

(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data.

(B) A color additive (i) shall be deemed unsafe, and shall not be listed, or any use which will or may result in ingestion of all or part of such additive, if the additive is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found to induce cancer in man or animal.

(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related

color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

Certification of Colors

(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health.

Procedure for Issuance, Amendment, or Repeal of Regulations

(d) The provisions of section 701 (e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

(1) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f)(2); and

(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

Fees

(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

Exemptions

(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

APPENDIX

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., May 29, 1959.

HON. SAM RAYBURN,
Speaker of the House of Representatives,
Washington, D.C.

DEAR MR. SPEAKER: We are enclosing herewith a draft bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on food, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. The bill may be referred to by the short title "Color Additive Amendments of 1959."

We respectfully urge the prompt consideration and enactment of this bill by Congress.

The bill is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs, or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

The principal reasons which give rise to the need for this legislation may be summarized as follows:

1. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection in that it does not allow us to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, we must ban the use of such a color completely, as not being "harmless," if it is found to be toxic in the laboratory when fed in some concentrations, even though its actual level and manner of use may be completely safe; for externally applied drugs and cosmetics the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use is wholly safe.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the Committee's report: "This Committee feels compelled to indicate that certification of a compound as 'harmless and suitable for use' in food, drugs, and

cosmetics as required under present law is unrealistic unless the level of use is specified."

2. The theoretically "perfect" public-health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While, theoretically, only "harmless" colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many, perhaps most, of the so-called colors on the list may in fact be toxic in some concentrations; yet we cannot take a particular color off the list until we establish its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which we could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

3. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At Present, there are no provisions for the certification of non-coal-tar colors; there is, moreover, no pretesting requirement for non-coal-tar color additives as such, other than food additives.

4. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation (Public Law 86-2) with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring oranges, after previous adoption of the safe-for-use principle in the Food Additives Amendment of 1958 (Public Law 85-929). The only reason we had suggested to Congress that the emergency legislation for citrus red No. 2 have a termination date was that color legislation limited to particular colors and articles of food is discriminatory and that permanent legislation on this subject should contain additional safeguards. Moreover, Public Law 86-2 on its face indicates the expectation that Congress will before long address itself to the problem of general color legislation.

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would

establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

A more detailed explanation of the principal changes made in existing law, and the reasons therefor, is attached to the draft bill. There is also enclosed herewith a section-by-section analysis of the bill.

The establishment of a tolerance system in this field requires, to an extent not involved in a system without tolerance limitations, a program of education of the user industries and public, and a program of enforcement activities by a thoroughly trained corps of inspectors and analysts. The fee provisions, which are the same as those under existing law for coal-tar colors, would defray only the cost of maintaining the listing and certification service; additional costs would be incurred for the enforcement and informational activities required by the establishment of a tolerance system. Enclosed herewith, as required by Public Law 801, 84th Congress, are statements of cost estimates and personnel requirements which would be entailed.

We should appreciate it if you would refer the enclosed draft bill, with the accompanying material, to the appropriate committee for consideration.

The Bureau of the Budget advises that there is no objection to the presentation of this proposed legislation to the Congress for its consideration.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*.

[Draft of bill which was introduced as H.R. 7624 omitted to conserve space.]

EXPLANATION OF PRINCIPAL FEATURES AND PURPOSES OF PROPOSED COLOR ADDITIVE AMENDMENTS OF 1959

The letter of transmittal briefly summarizes the general objectives of this legislative proposal, the principal reasons which gave rise to it, and previous amendments to the Federal Food, Drug, and Cosmetic Act which, in the case of food, show congressional endorsement of its key principle, that is, recognition of the scientific soundness of considering the level and other conditions of use in determining the safety of a color additive. A fuller explanation is, however, necessary to an adequate understanding of the major provisions of the bill and their purposes against the background of existing law. In addition, a section-by-section analysis is enclosed for the benefit of those who desire to become conversant with the details of each provision.

A. PRESENT LAW

Under present law, the treatment of color additives differs radically as between the so-called coal-tar colors and others. (For explanation of the technical difference between so-called coal-tar colors and others, see the discussion under "Major Changes Proposed.")

1. *Coal-tar colors*.—The act requires the Secretary to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, or cosmetics; and a food, drug, or cosmetic (other than a hair dye) is deemed adulterated if it bears or contains a coal-tar color other than from a certified batch (except that in the case of drugs this provision applies only where the

coal-tar color is used for coloring purposes only). (See secs. 402(c), 406(b), 501(a)(4), 504, 601(c), 604, and 701(e) and (f) of the act.) Under these provisions, we are without power to admit a color to listing under tolerance limitations. (*Flemming v. Florida Citrus Exchange*, 358 U.S. 153 (1958)).

2. *Other colors*.—A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirement in the case of cosmetics or drugs (except as pretesting may be required for a coloring component as an incident to official clearance of a “new drug” under the “new drug” provisions of the act).

On the other hand, with respect to their use in food, non-coal-tar coloring materials which are classed as “food additives” under the recent Food Additives Amendment of 1958 (Public Law 85-929) are subject to a requirement of official safety clearance, and to the establishment of tolerance limitations and other conditions of safe use where necessary for public health protection, except that colors which were in commercial use before January 1, 1958, are allowed a grace period for compliance; this period will expire not later than March 6, 1961. Such “food additive” colors, however, are not subject to any requirement of “batch” certification even if, in our view, this would be desirable for the protection of food processors and housewives using the color.

B. MAJOR CHANGES PROPOSED

The bill would change existing law in the following respects:

1. *Uniform criteria of admissibility*.—It would do away with the differences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics, other than hair dyes. This would be accomplished by excepting color additives, as defined in the bill, from the term “food additive”; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section (sec. 706), comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification (or exemption from certification); and making other amendments to the act to mesh with these provisions.

The term “coal-tar color” has been interpreted to apply not only to substances which are coal-tar derivatives, but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived. The present bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term “coal-tar color.” The bill would, therefore, establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer

protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, Delaney committee—see House Report No. 2356, and House Report No. 2182, 82d Congress—and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

2. *Safety-of-use principle.*—The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use, including maximum tolerance limitations, as are determined to be necessary to assure the safety of such use.

3. *Comprehensive lists.*—The bill, however, retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors “generally recognized” by experts as safe for use. While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color.

4. *Certification and exemptions from certification.*—While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color’s identity. We believe, however, that power to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

5. *Effective date and transitional provisions.*—The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act, that is, title I of the bill, would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification (or exemption from certification in certain cases). The “commercially established” color additives falling under these transitional provisions are (a) those coal-tar colors of

which a batch or batches were actually certified prior to the date of enactment of the bill, and (b) those non-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic, except that in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

C. NEED FOR THE BILL

The interests of consumer protection and of the food, drug, cosmetic; and color industries combine to make urgent the need for enactment of this bill.

1. Consumer protection

First.—Under present law the Government has to perform extensive research to determine whether the colors now listed and being used are in fact harmless and suitable for use in food, drugs, and cosmetics. This testing may require up to 20 years. The bill would require industry to assume the burden of this testing, and would require the tests to be completed within 2½ years or, in individual cases, such additional testing period as is shown to be required and to be consistent with public-health protection. Further, it would allow the Department to place safe tolerance limitations on the amount of color that may be used and the products on which it may be used during this transition period; the Department has no such authority under present law.

Second.—Other important aspects of consumer protection afforded by the bill are (a) that the pretesting requirement would be extended to those non-coal-tar colors, especially those used in cosmetics and drugs, to which it does not now apply, and (b) that the requirement of certification of batches of color, where necessary for the protection of the public health, would be extended to all colors.

Third.—The use of color in foods, drugs, and cosmetics, though largely of value from the point of view of enhancing the marketability of the articles involved, is, in many cases, also in the consumer's interest and affirmatively desired by consumers. This is obviously so not only in the case of cosmetics, many of which are designed and purchased for the very purpose of imparting color, but also in the case of certain foods, for example, margarine, where consumers demand artificial color. Housewives also frequently purchase certified color for use in home-prepared foods. In drugs, color additives are much used for ready identification, thus helping the pharmacist, the physician, the nurse, and the patient to avoid dangerous mistakes in choosing the wrong bottle or box. Thus, it is in the interest of the consumer that the law be changed so as to make available an adequate supply of colors of the safety of which, for particular uses, the consumer can be assured.

2. Commercial interests

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which, we believe, could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any way conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use (including tolerance limitations and certification requirements) established by this Department. Hence, while, as a consumer protection agency, we are concerned first and foremost with the protection of consumer interests, equity to the commercial interests concerned is also a factor in the submission of this proposal. It should, however, be stressed in this connection that we could not agree to a dilution or relaxation of the limitations of the carefully designed transitional provisions of this bill with respect to color additives which have heretofore been in commercial use.

The technical provisions and approach of this bill are summarized in detail in the section by section analysis enclosed herewith. Suffice it to say here that the bill includes, with necessary adaptations, the substantive safeguards for public health and consumer protection contained in the Food Additives Amendment of 1958 so recently considered and adopted by the Congress. ✓

SECTION-BY-SECTION ANALYSIS OF COLOR ADDITIVE AMENDMENTS
OF 1959

I. INTRODUCTION

Under existing law, so-called coal-tar colors are regulated under the Federal Food, Drug, and Cosmetic Act through similar sets of provisions in chapters IV (food), V (drugs), and VI (cosmetics). Food containing a coal-tar color is deemed adulterated by section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406; section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food, and to provide for certifying batches of such colors. A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504; section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors. A cosmetic (other than a hair dye (defined to exclude eyelash and eyebrow dyes)) containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604; section 604 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

Food colors which are not coal-tar colors are, when not generally recognized by experts as safe, regulated as "food additives" under the Food Additives Amendment of 1958 (Public Law 85-929). Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed adulterated if the additive is unsafe within the meaning of section 409; and under section 409, the food additive is deemed unsafe unless it and its use (or intended use) conform to a regulation under section 409 announcing the conditions under which the additive may be safely used.

The present bill takes "color additives" out of the scope of the Food Additives Amendment of 1958; repeals the present provisions for the listing and certification of "harmless" coal-tar colors (secs. 406 (b), 504, and 604); enacts new, integrated provisions for the separate listing of suitable "color additives" safe for use in food, drugs, or cosmetics, under such conditions (including tolerance limitations) as the Secretary may find necessary to assure the safety of the uses permitted; provides for the certification (or exemption from certification) of listed color additives for such permitted uses; adapts the adulteration and other provisions of the act to the substantive and other changes involved in the above-mentioned changes; and contains transitional provisions for commercially established colors.

II. SECTIONAL ANALYSIS

TITLE I. AMENDMENTS TO FEDERAL FOOD, DRUG, AND COSMETIC ACT

Section 101 amends section 201 (the definitional section) of the basic act as follows:

Section 101(a) of the bill redesignates section 201(s) of the basic act, defining the term "food additive," by excluding color additives from the term "food additive". While coal-tar colors are already, by

implication, outside the scope of the operative provisions of the Food Additives Amendment of 1958 (Public Law 85-929), the express exclusion of "color additives" makes clear that, beginning with the date of enactment of this bill, all color additives (as defined in sec. 101(c) of the bill) will fall outside the scope of the provisions on "food additives."

Section 101(b) of the bill redesignates section 201(t) of the basic act as section 201(u) and extends the definition of "safe" to apply to the use of that term in section 706 of the basic act as amended by section 103(b) of the bill.

Section 101(c) of the bill adds to section 201 of the basic act a new subsection (t), which defines the term "color additive" as any dye, pigment, or other substance, either synthetic or extracted or otherwise derived, which is capable of imparting color to a food-drug, cosmetic, or the human body, but excluding any material that the Secretary, by regulation, determines is used solely for noncoloring purposes. (Black, white, and intermediate grays are expressly included in the term "color.")

Section 102(a)

Paragraph (1) adds color additives to the exceptions from section 402(a) (2)(A) of the act, which now declares adulterated any food bearing or containing a poisonous or deleterious added substance which is unsafe within the meaning of section 406 of the act "except a pesticide chemical in or on a raw agricultural commodity and except a food additive." This paragraph of the bill makes explicit, with regard to color additives, the interpretation of the Supreme Court in *Flemming v. Florida Citrus Exchange* (358 U.S. 153 (1958)), that section 406(a) of existing law—which authorizes the establishment of tolerances for poisonous or deleterious substances added to food where the additive is required in the production of the food or cannot be avoided by good manufacturing practice—cannot serve as a basis for allowing the use of coal-tar colors where marketability of a food depends on such coloring. Under the bill, section 706 of the act would (except during a transitional period) provide the exclusive procedure for the listing (with or without tolerance limitations) and certification of color additives.

Paragraph (2) amends section 402(c) to deem a food adulterated if "it is, or it bears or contains," a "color additive" which is "unsafe within the meaning of section 706(a)" of the basic act as enacted by the bill. This would replace the present requirement of section 402(c) that deems adulterated a food bearing a coal-tar color which is not from a batch certified under section 406(b), and the provisos to section 402(c) with respect to the use of color on oranges (see Public Law 86-2). (Sec. 406(b) of the act would be repealed under another section of the bill). The effect of these changes would be to (a) make the new provisions applicable to all color additives, whether or not they are coal-tar colors; (b) extend them to the color additive itself before being added to food; and (c) use the technique of the Pesticide Chemicals Amendment and Food Additives Amendment by deeming the article adulterated if the additive is "unsafe" under another section (in this case the amended sec. 706) of the basic act which sets forth the criteria under which the additive shall be deemed unsafe.

Paragraph (3) adds to section 403 of the basic act a new subsection (l), whereby a food which is a color additive is deemed misbranded

unless packaged and labeled in accordance with packaging and labeling requirements, if any, contained in regulations issued under section 706 (as amended by the bill). (Under the basic act's definition of "food," a color additive intended to be added to food is itself considered "food" before it is so added.)

Section 102(b)

Paragraph (1) amends section 501(a)(4) of the basic act to deem adulterated any drug containing a color additive solely for purposes of coloring, and any color additive which (with respect to its use in or on drugs) is intended solely for coloring purposes, if these are unsafe within the meaning of section 706(a) of the act. This would replace the present provision of section 501(a)(4), which deems a drug adulterated if it bears or contains, for purposes of coloring only, a coal-tar color other than one from a batch that has been certified under section 504. (Sec. 504 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 502 of the basic act a new subsection (m) deeming misbranded a drug which is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with packaging and labeling requirements, if any, contained in regulations issued under section 706. (A color additive is, under the definition of "drug" in the basic act, itself a drug when intended for use as a component of drugs.)

Section 102(c)

Paragraph (1) amends section 601(e) of the basic act so as to deem adulterated a cosmetic (other than a hair dye) which is, bears, or contains a color additive which is unsafe within the meaning of section 706 of the act. This would replace the existing provision, which deems adulterated a cosmetic (other than a hair dye) which bears or contains a coal-tar color other than one from a batch certified under section 604. (Sec. 604 of the act would be repealed by another section of the bill.)

Paragraph (2) adds to section 602 of the act a new subsection (e) so as to deem misbranded a cosmetic which is a color additive (except a color additive for hair dyes) not packaged and labeled in accordance with packaging and labeling requirements, if any, under section 706. (Under the definition of "cosmetic" in the basic act, a color additive which is intended for use as a component of cosmetics is itself considered a cosmetic.)

Section 103

Subsection (a) repeals those sections (secs. 406(b), 504, and 604) of the basic act directing the Secretary to provide for listing, and certification of batches, of coal-tar colors which are "harmless and suitable" for use in food, drugs, and cosmetics, respectively; it also repeals the references to these sections in section 701(e) of the act. The saving provisions of 1 U.S.C., 109, will, of course, apply to these repeals.

Subsection (b) amends section 706 of the act to make more flexible and, incidentally, bring together within a single section of the act, the Secretary's rulemaking authority with respect to the use of color additives in or on food, drugs, or cosmetics. (Under present law,

sec. 706 contains only a provision which conditions the admitting to listing and certification of coal-tar colors upon the payment of fees. Cf. subsec. (e) of sec 706 as amended by the bill.) The major provisions of the proposed section 706 are:

Section 706(a).—The basic operative provision of the section, this subsection deems a color additive unsafe for a particular use (or intended use) in or on food, drugs, or cosmetics, for the purposes of the application of sections 402(c), 501(a)(4), and 601(e), of the act as amended by the bill, unless the color additive is listed under section 706(b) and complies with the conditions of use prescribed by the regulations listing the additive, and unless the additive is from a batch certified pursuant to regulations under section 706(c) or is exempted from the requirement of such certification. The single exception to these requirements is an exemption, to be provided by regulation (under sec. 706(f)), for color additives intended solely for investigational use by qualified experts.

Where a color additive is used in accordance with the Secretary's regulations, it is also exempted from the general provisions that deem adulterated any food (sec. 402(a)(1)) or cosmetic (sec. 601(a)) bearing or containing a poisonous or deleterious substance that may render it injurious to health. This exempting provision does not apply to hair dye (other than eyebrow and eyelash dye), since coal-tar hair dyes are not covered by section 601(e) of the act.

Section 706(b).—Paragraph (1). The Secretary is required to establish separate lists of color additives for use in respect to food, drugs, and cosmetics, to the extent that the additives are safe for use when employed in accordance with the regulations listing them.

Paragraph (2). The listing of an additive may be for general use in respect to food, or drugs, or cosmetics, or it may be for a more limited use.

Paragraph (3). The regulations listing the color additive must, to the extent deemed necessary to assure safety of use, prescribe tolerance limitations, other directions relating to the manner of adding or using the additive, labeling or packaging requirements for such additive, and other conditions.

Paragraph (4). A color additive may be listed for use only where it affirmatively appears that the additive may safely be used under the conditions to be prescribed by regulation; and that there are practicable methods for analyzing its contents, and for determining the identity and quantity of such additive in or on any article of food, drug, or cosmetic, and of any substance formed in an article because of the use of the additive. (Cf. secs. 409(b)(2)(D) and 409(c)(3) of the act, relating to food additives.)

Paragraph (5). In determining whether the use of a color additive is safe, the Secretary is required to consider a broad range of factors. In particular, however, a color additive may not be listed if it has relevant carcinogenic potential. (This paragraph is modeled on sec. 409(c)(5) and the proviso to sec. 409(c)(3)(A) of the act, relating to food additives.)

Paragraph (6). The Secretary may not list a color additive for a proposed use if that use would promote deception of the consumer or otherwise result in a misbranding or adulteration within the meaning of other provisions of the act. (A similar provision is contained in sec. 409(c)(3)(B) of the act for food additives.)

Paragraph (7). If a tolerance limitation is required to assure safety, a color additive may not be listed unless the data establish that, if used within a safe tolerance, the additive will achieve the intended physical or other technical effect; and the permissible tolerance may be set no higher than the level necessary to accomplish this effect. This requirement is similar to that imposed on the Secretary by section 409(c)(4) of the act with respect to food additives.

Paragraph (8). Where, because of the aggregate quantity of a color additive (or pharmacologically related additives) likely to be involved, the Secretary cannot list the color (or colors) for all proposed uses, he may select among those uses or may apportion the aggregate allowable tolerance among them, subject to the paramount criterion of safety. For the purpose of such selection or allocation, the bill provides for taking into account, among other relevant factors, the marketability of an article as affected by color, and industry dependence on the color uses involved; the quantities of color consumption involved in the various color uses; and the availability of other colors.

Section 706(c).—Directs the Secretary to provide for the certification of batches of color additives, and for exemption from the requirement of certification where unnecessary in the interest of the public health. Under this subsection, the Secretary could provide for conditioning certification of batches of color additives on the keeping of records of disposal, as he does under existing law.

Section 706(d).—This subsection, in general, incorporates by reference the procedures of section 701(e)–(g) which now govern coal-tar colors, except that it adopts the provisions as to “fair evaluation on the basis of the entire record” enacted by the Food Additives Amendment of 1958.

In discussing the provisions of the Food Additives Amendment of 1958 which the present bill incorporates by reference, Assistant Secretary Elliot L. Richardson, in a letter to the chairman of the House Committee on Interstate and Foreign Commerce, dated August 8, 1958, and reprinted in the Congressional Record, stated:

“The Secretary’s action after hearing would have to be based upon a fair evaluation of the entire record at the hearing. On judicial review, the U.S. court of appeals would be required to sustain the findings of the Secretary if based upon a ‘fair evaluation of the entire record at the hearing’; it would have to reverse the order of the Secretary if it is not ‘based upon a fair evaluation of the entire record’ or if it fails to include a statement setting forth in detail the findings and conclusions upon which the order is based. The ‘fair evaluation’ provision is quite acceptable to the Department, because it is the standard to which we are accustomed to adhere” (Congressional Record, 85th Cong., 2d sess., Aug. 13, 1958, p. 16016).

The “fair evaluation of the entire record” standard thus is to govern the action of the Secretary after hearing, and to be used as a criterion by the reviewing court in passing on the validity of the Secretary’s action, not merely as respects findings of fact but as respects his action as a whole. It, in effect, extends to rulemaking the approach to judicial review of administrative adjudication taken in *Universal Camera Corporation v. N.L.R.B.*, 340 U.S. 474 (1951), and attempts to encapsule in a phrase the requirements of the Administrative Procedure Act as to fairness as opposed to arbitrariness, caprice, and abuse of discretion.

Section 706(e).—This subsection contains the fee provision (with the reference to coal-tar colors amended to refer to color additives) contained in section 706 under existing law. Under the amended act fees for admitting a color to listing would necessarily include the cost of setting tolerance limitations authorized by section 706(b).

Section 706(f).—The Secretary is required to provide, by regulation not subject to the above-mentioned procedure, for exempting from the operation of section 706 any color additive or use thereof intended solely for investigational use by qualified experts, when such exemption is consistent with the public health. A similar exemption exists in section 409(i) of the act for food additives.

Section 104

Extends section 301(j) of the basic act, which prohibits the revelation and the personal use of trade secrets acquired under the authority of various sections of the act (including sec. 409, relating to food additives), so as to include information obtained under the proposed section 706.

Section 105

Contains appropriate changes of cross-references in, and other conforming amendments to, sections 301(i) (false use of required marks), 303(c)(3) (guarantee that coal-tar color is certified), and 402(d) (non-nutritive substances in confectionery) of the basic act.

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Section 201

Defines, for the purposes of title II, the term “basic act” as the Federal Food, Drug, and Cosmetic Act; the term “enactment date” as the date of enactment of the bill; and other terms, insofar as also used in the basic act (whether before or after enactment of the bill) as having the same meaning as they have, or had when in effect, under the basic act.

Section 202

Makes the bill effective upon enactment, subject to the transitional provisions of section 203.

Section 203

Subsection (a)(1) declares that this section is intended to make possible, for a reasonable interim period, through provisional listings, the continued use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific tests needed as a basis for making determinations with respect to the definitive listing of such additives under the basic act.

Subsection (a)(1) also directs that a provisional listing (which, while in effect, has the same effect as a listing under sec. 706 of the basic act) shall, if not sooner terminated, expire (i) on the “closing date” or (ii) on the effective date of the additive’s listing under section 706, whichever date first occurs.

Subsection (a)(2) defines “closing date” as the last day of the 2½-year period beginning on the enactment date, except that, with respect to a particular provisional listing, the Secretary could postpone the original closing date for such period or periods as he finds necessary

to carry out the declared purpose of this section, if consistent with the objective of completing in good faith, as soon as practicable, the necessary scientific tests needed to make a determination with respect to listing under section 706 of the basic act. Such postponements could be terminated if they should not have been granted, or on change of circumstances, or on failure to submit required progress reports or meet other conditions.

Subsection (b): First, colors subject to those provisions of present law (secs. 406(b), 504, or 604, or the third proviso to sec. 402(c)) which require the listing and certification of so-called coal-tar colors, are deemed provisionally listed for any use for which they were actually listed under these provisions on the day preceding the enactment date if a batch or batches of the color had been certified prior to that date. Second, a color additive which is either synthetic beta-carotene or which, on the date preceding the enactment date, was not within the purview of the so-called coal-tar color provisions of the law, is deemed provisionally listed under the bill for any use of the color for which it was commercially used or sold prior to the enactment date. (It should be noted that the term "coal-tar color"—which under existing law is interpreted as including synthetic colors which, though not coal-tar derivatives, are so chemically structured as to be capable of being derived from coal tar—is not used in the bill. Synthetic beta-carotene is separately dealt with in the bill because its classification with coal-tar colors under existing law is in dispute and has been the subject of a hearing.)

Subsection (c) requires the Secretary, upon request, to list provisionally any color for any use for which it had been listed, and for which use a batch had actually been certified, under the above-mentioned coal-tar color provisions of existing law prior to the enactment date, although it was not so listed on the day preceding that date, if he deems such action consistent with protection of the public health.

Subsection (d)(1). The Secretary is directed, so far as practicable, (A) to promulgate and maintain current a list of color additives deemed provisionally listed, (B) to provide for provisional listing of color additives upon request in accordance with subsection (c), (C) to prescribe, if needed for public-health protection, temporary tolerance limitations (including zero tolerances), and other conditions of use for color additives provisionally listed, (D) to provide for the certification of batches of provisionally listed color additives (except that a color additive deemed provisionally listed under subsection (b)(2) shall be deemed exempt from certification while not subject to a tolerance); and (E) to provide for the termination of a provisional listing forthwith where necessary to protect the public health.

Subsection (d)(2). Regulations under this section are not subject to the procedural requirements of the Federal Food, Drug, and Cosmetic Act, but fees shall be charged (and be available for use) as though the regulations and other proceedings under this section had been under section 706 of the basic act as amended by the bill. On and after the starting date, provisional listing and certification under this section shall have the same effect as listing and certification under section 706 for the purpose of determining whether an article is adulterated or misbranded, but provisional listings and other actions under section

203 of the bill shall not give rise to any presumption or inference in section 706 proceedings.

Subsection (d)(3). In order that the Secretary may be able to promulgate and keep current a list of color additives deemed to be provisionally listed and to prescribe temporary tolerance limitations and other conditions of use with respect to those additives, he is directed to afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data submitted or otherwise before the Secretary do not reliably enable him to include a color in the published list of color additives deemed to be provisionally listed, or to ascertain the levels of use of such an additive prevailing prior to the enactment date, the Secretary is directed to fix a temporary zero tolerance for such colors or uses thereof until he deems a higher tolerance, or the absence of a tolerance limitation, consistent with the public interest.

Section 204

Makes clear that the bill, when enacted, would not relieve any meat or meat food product or any person from any requirement under the Meat Inspection Act of March 4, 1907, as amended or extended (21 U.S.C. 71 et seq.), or the Poultry Products Inspection Act (21 U.S.C. 451 et seq.).

Department of Health, Education, and Welfare—Estimate of cost of enforcement of proposed Color Additive Amendments of 1959 as required by Public Law 801, 84th Cong.¹

	Fiscal year—									
	1960		1961		1962		1963		1964	
	Man-years	Cost	Man-years	Cost	Man-years	Cost	Man-years	Cost	Man-years	Cost
Estimated maximum additional.....	59	\$1,080,000	112	\$886,900	112	\$886,900	112	\$886,900	112	\$886,900
Man-years of civilian employment, by general categories of positions:										
Technical.....	4	-----	8	-----	8	-----	8	-----	8	-----
Scientific.....	25	-----	47	-----	47	-----	47	-----	47	-----
Inspectional.....	13	-----	24	-----	24	-----	24	-----	24	-----
Laboratory aid.....	6	-----	11	-----	11	-----	11	-----	11	-----
Clerical.....	11	-----	22	-----	22	-----	22	-----	22	-----
Total.....	59	-----	112	-----	112	-----	112	-----	112	-----
01 Personal services.....		340,500		648,300		648,300		648,300		648,300
02 Travel.....		14,900		28,400		28,400		28,400		28,400
03 Transportation of things.....		9,200		2,900		2,900		2,900		2,900
04 Communication services.....		3,500		6,700		6,700		6,700		6,700
05 Rents and utility services.....		345,000		90,000		90,000		90,000		90,000
06 Printing and reproduction.....		3,600		6,900		6,900		6,900		6,900
07 Other contractual services.....		11,400		21,700		21,700		21,700		21,700
08 Supplies and materials.....		20,900		39,800		39,800		39,800		39,800
09 Equipment.....		308,800		42,100		42,100		42,100		42,100
10 Grants, subsidies, and contributions.....		22,100		100		100		100		100
11 Taxes and assessments.....		100		-----		-----		-----		-----
Total estimate.....		1,080,000		886,900		886,900		886,900		886,900

¹ These estimates are in addition to fees to be collected for admitting color additives to listing and certifying batches thereof.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
August 7, 1959.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: We understand that representatives of some of the industries that would be affected by H.R. 7624 (to be known as the Color Additive Amendments of 1959) have suggested an amendment to the bill relating to the requirements concerning analytical methods for color additives.

Under the bill in its present form (p. 9, lines 3-16), the proposed section 706(b)(4) of the Federal Food, Drug, and Cosmetic Act would preclude the Secretary from listing a color additive for any use in or on food, drugs, or cosmetics unless the data before him establish—

“(A) that such use, under the conditions of use to be specified in the regulations, will be safe;

“(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and

“(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive.”

The proposed amendment suggested by industry representatives could consolidate the matter contained in the above-quoted paragraphs (B) and (C) and, with appropriate editorial revision, transfer it to section 706(b)(5), which begins on the same page and enumerates some of the most important factors which the Secretary must consider in passing on the safety of a proposed use of a color additive. As so amended, section 706(b)(4) and (5), beginning on page 9, line 3, and ending on page 10, line 10, of the bill, would read as follows:

“(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe.

“(5)(A) in determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

“(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

“(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

“(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

“(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food,

drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive."

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analyses are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe.

The purpose of the requirement of the bill that there be practicable methods of analysis for determining the quantity of the pure dye and all intermediates and other impurities contained in a color additive is to enable the manufacturer of the color, and also this Department where we are asked to certify batches of color, to determine that the color in actual practice meets the requirements for purity and the definitional standards of our regulations, and to facilitate enforcement. The purpose of the other requirements as to available practicable methods of analysis is to make possible effective enforcement of any conditions or limitations that may be put on the listing of a color for use in foods, drugs, or cosmetics. We, of course, regard practicability and facility of enforcement as essential elements of safety in determining whether a proposed use of a color additive is safe within the meaning of the bill.

There are many circumstances where it would be necessary to have practicable analytical methods for all or most of the above-mentioned purposes. We can, however, visualize some situations in which these analytical methods, or some of them, would not be necessary for any of the purposes which we have mentioned and would thus not be essential in the interest of sound public health protection. We therefore recognize that in requiring such analytical methods to be available in all cases without regard to actual need the original bill goes further than absolutely necessary for public health protection.

Under the proposed change, we would consider ourselves bound to require those analytical methods specified in the bill for which, on the basis of our general knowledge or on the basis of the particular situation, we find that there is a need for the above-mentioned purposes, or otherwise in the interest of safeguarding the public health, and we would therefore feel bound to refuse to list a color where such needed methods are not available. At the same time, the proposed amendment would relieve us of the necessity of imposing these requirements where they are not needed.

We therefore would not object to the proposed change in the bill.

The Bureau of the Budget advises that it perceives no objection to the submission of this report to your committee.

Sincerely yours,

ELLIOT L. RICHARDSON,
Assistant Secretary.

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
February 8, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: It has come to my attention that two questions have been raised concerning the scope of the proposed color additives legislation now being considered by your committee (S. 2197 and H.R. 7624). Since these questions were not covered by my testimony on January 26, I am taking this opportunity of letting you have the views of our Department on them.

A representative of the packaging industry has expressed to us an apprehension that the Department's proposed legislation might be construed as applying to coloring materials used in food wraps and other food packaging materials even where the color does not migrate from the wrap to the food or, if there is migration, where it is so slight that it would cause no color in food discernible by the unaided eye.

It is our view that the color additives amendment would not apply to color materials in food wraps that do not migrate from the wrap to the food.

Additionally, it is our view that the bill is intended to regulate substances that color or are capable of coloring food to a degree apparent to the naked eye. Thus, a component of food packaging that migrated into food but did not change its color in the ordinary sense of the term would continue to be regulated, if necessary, under the food additives amendment and would not become subject to the proposed color additives bill.

The second question relates to pesticide chemicals as defined in section 201(q) of the Federal Food, Drug, and Cosmetic Act. We are advised that certain fungicides used in fruit production have the effect not only of protecting the tree against plant diseases but also of effecting or supporting natural plant processes so the plant produces better color and finish in the fruit; and some plant growth regulators, when applied to plants, likewise enhance the development of normal color in produce derived from them.

It is our view that pesticide chemicals used in this way are not color additives within the meaning of the proposed legislation and do not impart an artificial color to the raw agricultural commodities. Rather, they promote the development of the natural color of produce as a result of the normal physiological processes of the plant. The legislation which we drafted was not intended to apply to pesticide chemicals which enhance color by affecting or supporting natural plant processes and we would expect to continue to regulate pesticide chemicals, if the bill is enacted in its present form, under the pesticide chemicals amendment and not the color additives amendment.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
April 11, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: The purpose of this letter is to recommend a correction in the hearing provision in title I of the proposed "Color Additive Amendments of 1959" (H.R. 7624 and S. 2197) now pending before your committee.

As drafted by this Department and submitted to Congress, and as contained in these bills, the hearing provision would, through an inadvertent cross-reference to the subsection on fees, provide for hearing and judicial review not only with respect to the issuance, amendment, or repeal of regulations relating to the listing and certification of color additives, but also with respect to regulations establishing fees for such listing and certification.

Under present law as consistently interpreted by us since its enactment, the issuance or amendment of regulations establishing schedules of fees for the listing and certification of coal-tar colors is not subject to hearing or judicial review (section 706 of Federal Food, Drug, and Cosmetic Act). This likewise holds true in the case of fees for certification services for insulin or antibiotics, fees for the pesticide regulation service, and fees for seafood inspection (sections 408(o), 506, 507, 702A). The establishment of such fees is purely a matter of cost accounting and, since the services must be self-sustaining, the fees are automatically kept at the appropriate level through auditing of expenditures by the General Accounting Office. To provide for hearing and judicial review with respect to the establishment of fees would thus serve no useful purpose and, on the other hand, might cause delay which could seriously impede or make impossible the performance of the services in question.

We therefore recommend that the provisions of these bills be corrected by changing the phrase "subsections (b), (c), or (e) of this section" (H.R. 7624, p. 13, line 6; S. 2197, p. 13, line 9) to read "subsection (b) or (c) of this section."

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
Washington, D.C., April 21, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN. On January 29, you indicated during the hearings on pending color additive legislation (H.R. 7624 and S. 2197) that you would like to have our views on the various amendments proposed by witnesses other than those representing this Department. Accordingly, we have reviewed the record of the hearings and are glad to offer the following comments.

The amendments proposed by the witnesses fall into four principal categories:

1. There are a number of suggestions for change in the scope of the bills.

2. There are several recommendations with respect to the substantive criteria for listing colors, including a number of adverse comments on the anticancer clause in the Department's proposal as contained in H.R. 7624. The criticisms of the bill's anticancer clause also extend to the clause from which it is derived, i.e., the so-called Delaney proviso in the Food Additives Amendment of 1958.

3. A number of suggestions are made on procedural points, both with respect to the permanent part (title I) and the transitional part (title II) of the bill.

Additionally, one individual, Mr. Frank Schell, of Florida, has written to the committee proposing an entirely new bill to be substituted for the Department's bill.

Our comments on these various items, except the anticancer clause are enclosed herewith (enclosure I). I expect to testify further on the anticancer clause. There is enclosed herewith (enclosure II) a draft of a provision which would accord an opportunity for hearing with respect to certain regulatory actions under the transitional part of the bill, under the conditions stated in my testimony. There is enclosed (enclosure III) a draft amendment to the proposed section 706(d) of the bills, to incorporate time limits in the rulemaking procedure of the legislation if the committee should wish to do so. Also there is enclosed (enclosure IV) a draft amendment to section 203(d)(2)(A) of the bill to make it clear that funds and regulations dealing with the cost of certifying coal-tar colors under section 706 of the basic act, shall continue to be available and in effect, respectively, for the purposes specified in section 706 as amended by the proposed bill.

In summary, we are opposed to all the amendments proposed by the witnesses, except (1) a clarifying amendment on agricultural chemicals, in the form contained in enclosure I agreed upon by us with the Department of Agriculture, and (2) the amendments set forth in enclosures II and III. As between the respective versions of S. 2197 and H.R. 7624, we have already advised that the changes contained in S. 2197 as passed by the Senate are acceptable to us, except that we recommend inclusion of the anticancer clause of H.R. 7624 with a modification relating to animal feed similar to the one we are developing for the Delaney proviso to the Food Additives Amendment of 1958. We have also recommended, by letter dated April 11, 1960, a technical correction in section 706(d).

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary*.

[Enclosure 1]

COMMENTS ON AMENDMENTS TO S. 2197 OR H.R. 7624,

PROPOSED BY NONGOVERNMENTAL WITNESSES

I. SCOPE OF BILL

1. *Nature, source, or type of action of the coloring material*

(a) * * *

(b) *Agricultural chemicals*.—Several witnesses suggested that pesticide chemicals be exempted from the coverage of the color additives legislation. A representative of the National Agricultural Chemicals Association, on the other hand, indicated that the Department's

position as to the interpretation of the bill—i.e., that chemicals affecting color of fruit or other produce merely through their effect on plant metabolism do not “impart color” within the meaning of the bills—as submitted in our letter of February 8, 1960, to you, would meet the needs of the association. However, by letter, the association has, we understand, requested that this position be incorporated in the language of the bill rather than left to legislative history. The Department of Agriculture also favors this. We have no objection to incorporating the position in the bill itself and suggest that the following language—jointly developed by this Department and the Department of Agriculture, and submitted to the committee by that Department by letter dated April 14, 1960—be added as subparagraph (3) to the definition of the term “color additive:”

“(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.”

More sweeping language suggested by the association and some other witnesses, which would mandatorily exempt a pesticide chemical even though that chemical also acts as a dye would be seriously objectionable since it would result in our list of food colors being incomplete and would admit of circumventing the certification provisions of the bill through the development of combined pesticide-dye chemicals. We invite attention to the fact that the bill already excepts from the term “color additive” any material “which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.”

* * * * *

To avoid any misunderstanding, we emphasize that the Department has no objection to the artificial coloring, under proper labeling declaration, of mature oranges. We have given this assurance to the citrus industry, we have stated it for the record at the hearings on the present bills, and we repeat it here.

* * * * *

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE,
May 13, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: On May 9, 1960, when I appeared before your committee with regard to proposed color additives legislation, you requested that we comment on a proposal that has been made for amending the anticancer clause of H.R. 7624. As we understand the proposal, it would change section 706(b)(5)(B)(i) so that it reads:

“(B) A color additive (i) shall be deemed unsafe and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, ~~if the additive is found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of additives for use in food, to~~

induce cancer in man or animal, * * *." (Interlined material present in original bill, but to be deleted.)

The deletion of the interlined language from the proposed color additives bill, and deletion of comparable language from the anticancer clause of the Food Additives Amendment of 1958, in view of the past history of the anticancer clauses, is obviously designed to weaken the anticancer clause and to allow room for the contention that our Department should establish tolerances to permit chemicals in food even though they had been found to induce cancer when fed. This would serve no purpose except to lead to extended litigation on this issue in the courts.

As you know from my testimony on January 26 and again on May 9, 1960, we believe there is no sound scientific basis at this time for establishing tolerances to allow carcinogens to be added to food.

We recommend that the proposed change not be adopted.

Sincerely yours,

ARTHUR S. FLEMMING, *Secretary.*

DEPARTMENT OF HEALTH, EDUCATION AND WELFARE,
Washington, May 13, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: As you know, in my testimony before your committee on the color additive bills (H.R. 7624, S. 2197), I explained the need for modification of the Delaney (anticancer) proviso in the Food Additives Amendment of 1958 insofar as animal feed is concerned, and the need for modification of the so-called grandfather clause (sec. 201(s)(3)) of the food additives amendment, and stated that we were developing language to carry out these recommendations. I also suggested that adoption of a parallel modification of the anticancer clause of H.R. 7624 would be appropriate concomitantly with modification of the Delaney proviso. ✓

At the close of my last appearance before the committee, you requested that we submit the technical language which we had in mind to carry out our recommendations, and you indicated that the record would be held open to the end of this week.

We are therefore enclosing, for the consideration of the committee, proposed amendments to the pending color bills which would carry out these recommendations. The two amendments on food additives are in a measure complementary to each other and, we believe, should be enacted at the same time. In view of their urgency, and the close relation of one of these amendments to the proposed modification of the anticancer clause of H.R. 7624, we hope that they will be included in the pending legislation.

There is also enclosed herewith a further explanation of the need for, and purposes of, the proposed changes in the Food Additives Amendment of 1958.

We should appreciate the inclusion of this letter and of the enclosures in the record of the hearings on H.R. 7624 and S. 2197.

We are advised by the Bureau of the Budget that it perceives no objection to the submission of these proposals.

Sincerely yours,

ARTHUR S. FLEMMING,
Secretary.

PROPOSED AMENDMENTS TO H.R. 7624 OR S. 2197, 86TH CONGRESS,
TO CARRY OUT CERTAIN RECOMMENDATIONS MADE IN TESTIMONY
OF THE SECRETARY OF HEALTH, EDUCATION, AND WELFARE

A. AMENDMENTS RELATING TO FOOD ADDITIVES

1. Amend page 1, lines 3 and 4, of the bill to read: "That titles I and II of this Act may be cited as the Color Additives Amendment of 1960, and title III of this Act may be cited as the Food Additives Amendment of 1960."

2. Insert in the caption of title I of the bill (p. 2, line 1), after the dash, the words "COLOR ADDITIVE", and add at the end of the bill the following new title (containing two sections):

"TITLE III—AMENDMENTS AS TO FOOD ADDITIVES

"MODIFICATION OF PRIOR SANCTION (GRANDFATHER) CLAUSE

"SEC. 301. The last numbered clause of section 201(s) of the Federal Food, Drug, and Cosmetic Act (which clause is redesignated as clause (4) by section 101(a) of this Act) is amended by inserting in such clause, before the period, a colon and the following: '*Provided*, That, with respect to any sanction or approval granted pursuant to this Act, this clause shall be inapplicable, and the provisions of this Act (other than this clause) relating to food additives shall apply, to any such previously sanctioned or approved use of a substance if, on the basis of the information then available, the Secretary finds that, for the reasons set forth by him, there is reasonable doubt as to its safety. Except when the Secretary finds that there is an imminent hazard to public health, he shall take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public, and only after sending reasonable notice of his proposed action and the reasons therefor to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised thereof unless such personal notice is impracticable.'

"MODIFICATION OF ANTICANCER PROVISIO

"SEC. 302. The proviso to clause (A) of paragraph (3) of section 409(c) of such Act is amended by inserting before the semicolon at the end of such proviso the following: ', except that this proviso shall not apply with respect to the use of a substance as an ingredient of feed for animals which are raised for food production, if the Secretary finds (i) that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and (ii) that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsections (f)

and (g)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal'."

B. MODIFICATION OF COLOR ADDITIVE ANTICANCER CLAUSE IN H.R. 7624
(SEC. 706(b)(5)(B))

Insert before the period at the end of section 706(b)(5)(B) (p. 10, line 22, of H.R. 7624) a colon and the following proviso: "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal".

NOTE.—If, in view of certain Senate committee amendments (accepted by this Department) to the Senate companion bill, S. 2197 (which bill, as introduced and passed by the Senate, has no anticancer clause), it is desired to use S. 2197 as a basis for action, S. 2197 (as passed by the Senate) should be amended by—

- (1) inserting "(A)" after "(5)" on page 9, line 20, of that bill;
- (2) redesignating clause "(A)", beginning on page 9, line 23, as clause "(i)";
- (3) redesignating clause "(B)" (p. 10, line 4) as clause "(ii)";
- (4) redesignating clause "(C)" (p. 10, line 8) as clause "(iii)";
- (5) redesignating clause "(D)" (p. 10, line 14) as clause "(iv)" and redesignating subclauses (i), (ii), and (iii) in that clause (p. 10, lines 16, 17, and 19) as "(I)", "(II)", and "(III)", respectively; and
- (6) inserting on page 10, between lines 20 and 21, the anticancer clause now contained in H.R. 7624 (p. 10, lines 11–22) as modified by the above-quoted proviso.

The above, suggested changes in S. 2197 assume that the committee will also accept the present version of section 706(b)(4) of the Senate bill, which we have accepted.

EXPLANATION OF NEED FOR, AND PURPOSES OF, ENCLOSED DRAFT
AMENDMENTS TO GRANDFATHER CLAUSE AND ANTICANCER (DE-
LANEY) PROVISIO OF FOOD ADDITIVES AMENDMENT OF 1958 (FOR
INCLUSION IN COLOR ADDITIVE BILL WITH PARALLEL MODIFICA-
TION (ALSO ENCLOSED) OF ANTICANCER CLAUSE OF H.R. 7624)

The enclosed draft amendments to the color additive legislation would make two changes in those provisions of the Federal Food, Drug, and Cosmetic Act which were added to that act by the Food Additives Amendment of 1958 (Public Law 85-929), approved September 6, 1958.

Prior to the enactment of that amendment, pretesting and safety-clearance requirements applied, in general, under the act only to so-called pesticide chemicals used in or on raw agricultural commodi-

ties (as provided by Public Law 518, 83d Cong.), except that drugs used in animal feed or in other food, or administered directly to animals raised for food production, were subject to safety clearance under the new-drug provisions of the act (sec. 505). The Food Additives Amendment of 1958 (Public Law 85-929) further strengthened the public-health protection afforded by the act, by prohibiting any food additive which has not been adequately tested to establish affirmatively its safety for food use as determined through a safety-clearance procedure established by that amendment.

The underlying philosophy of the Food Additives Amendment of 1958 is that any reasonable doubt as to the safety of an additive should be resolved against permitting its use. Moreover, in line with this basic philosophy—and in the light of scientific evidence before the House committee that present scientific knowledge is not sufficient for determining a safe tolerance for the human diet in the case of a substance which, when included in the diet of test animals or otherwise administered to such animals through relevant tests, induces cancer in such animals—the Congress inserted in the law a proviso (known as the Delaney proviso) which bars a substance completely for food use if it is “found to induce cancer when ingested by man or animal, or if it is found, after tests which are appropriate for the evaluation of the safety of food additives, to induce cancer in man or animal.”

The experience so far had under Public Law 85-929, however, has disclosed a need for two modifications of the food additives amendment which would better carry out its public-health objective and remove certain inequities.

1. Grandfather clause

In enacting the Food Additives Amendment of 1958, Congress decided, in accordance with our recommendations, that in view of its public-health objective it should in general apply not only to new additives and new uses of existing additives, but also to uses of additives already commercially established, subject to transitional provisions intended to allow a reasonable time for compliance with the new pretesting requirements and safety-clearance procedure. However, in order to avoid useless paperwork, the amendment excluded from its scope two categories of additives (in addition to pesticide chemicals for raw agricultural commodities), i.e., any additive which is generally recognized by experts as safe (such as salt, pepper, sugar, etc.) and also “any substance used in accordance with a sanction or approval granted prior to the enactment of [the Food Additives Amendment] pursuant to [the Federal Food, Drug, and Cosmetic] Act, the Poultry Products Inspection Act (21 U.S.C. 451 and the following) or the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. 71 and the following).”

Thus, while the last-quoted clause (which is now sec. 201(s)(3), but will be redesignated by the color additive bills as sec. 201(s)(4), of the Federal Food, Drug, and Cosmetic Act) is often for convenience referred to as the “grandfather” clause of the Food Additives Amendment, its purpose was not to confer any vested right in a prior sanction or approval of an additive, but merely to avoid the need for pro forma resort to the safety-clearance procedure of the amendment when the safety of the additive and of its particular use has been satisfactorily established through a prior sanction or approval. It was clearly

understood that the so-called "grandfather" clause would be applicable only so long as the prior sanction or approval remained in effect and that, as stated in the explanation of this Department's draft bill from which the Food Additives Amendment was derived, the clause "would not prevent rescission of such a sanction or approval, and subsequent inclusion of the additive under the bill, if the particular use of the additive is subsequently found to be toxic or of doubtful safety." (Hearings on food additives before a subcommittee of the House Committee on Interstate and Foreign Commerce, 85th Cong. (1957 and 1958), p. 28, at p. 35.) (See also 21 C.F.R., sec. 121.3; 24 F.R. 2434, Mar. 28, 1959, which established certain notice requirements for withdrawal or modification of such a prior sanction or approval.)

In submitting the grandfather clause to Congress, we had primarily in mind official advice contained in letters of the Food and Drug Administration (so-called trade correspondence) to members of the food and chemical industries in response to inquiries from them with respect to the interpretation or application of the Federal Food, Drug, and Cosmetic Act. Such advice, not being legally binding, could, of course, be withdrawn at any time without formal proceedings. However, there are also in effect certain prior "sanctions" or "approvals" under the act—particularly those granted for new drugs under section 505 of the act—which, though granted in the first instance only on the basis of what was considered an affirmative showing of safety, cannot thereafter be withdrawn unless the original application contained an untrue statement of a material fact or unless the Government can establish—on the basis of clinical experience, new test methods, or methods not previously deemed reasonably applicable—that the article is unsafe. This situation, of course, is contrary to the underlying premise of the grandfather clause that the grandfather clause would always become inapplicable when a previously sanctioned use of a chemical additive to food was found to be of doubtful safety. The law should make it very clear that establishing merely a reasonable doubt as to the safety of any additive, in the light of all available data, would be an adequate basis for withdrawal of any sanction or approval with respect to it.

This creates a situation which is inconsistent with the above-mentioned basic philosophy and public-health objective of the Food Additives Amendment, and, in the case of a cancer-inducing chemical, with the anticancer proviso of that amendment. In the second place, it operates inequitably as between a person who holds an effective new-drug application, antedating Public Law 85-929, with respect to a drug manufactured by him for food use and who is thus protected by the grandfather clause because it is not shown to be unsafe but on which there may be doubt as to its safety, and another person who desires to make and market the same drug for the same purpose but who does not come within the grandfather clause and cannot obtain clearance under the Food Additives Amendment because the drug is banned by the anticancer proviso or because for other reasons its safety cannot be affirmatively demonstrated.

We therefore recommend amendment of the grandfather clause so that, whenever on the basis of the information available to the Secretary, he finds (after appropriate notice) that there is reasonable doubt as to the safety of the use of an additive sanctioned or approved pur-

suant to the Federal Food, Drug, and Cosmetic Act before enactment of Public Law 85-929, the grandfather clause will, with respect to that sanction or approval, no longer apply, and the safety-clearance requirements of the Food Additives Amendment will apply, without regard to any other requirements of the act relating to suspension or revocation of such previous sanction or approval. If, in such a case, the additive is a carcinogen, this, of course, will mean that it is thereafter subject to the above-quoted anticancer (Delaney) proviso, except as proposed below with respect to animal feed.

2. Modification of Delaney proviso

According to advice of our scientists, the principle of the above-quoted anticancer (Delaney) proviso of the Food Additives Amendment reflects, basically, the current state of scientific knowledge, and we would therefore, except as noted below, feel constrained to apply the same principle even in the absence of this proviso, and we do in fact apply it in the administration of the Pesticide Chemicals Amendment which does not contain the proviso.

There is, however, one respect in which the anticancer proviso has proved to be needlessly stringent as applied to the use of additives in animal feed. For example, in the case of various animals raised for food production, certain drugs are used in animal feed which will leave no residue in the animal after slaughter or in any food product (such as milk or eggs) obtained from the living animal, and which are therefore perfectly safe for man. If this is demonstrated with respect to any particular additive intended for animal feed, and the additive will not adversely affect the animal itself during its expected or intended life cycle, we can see no reason for not permitting such a use of an additive which could be highly useful and beneficial in the raising of animals for food. The condition that the additive must not adversely affect the animal is, of course, necessary, for, even in the absence of the anticancer proviso, the Food Additives Amendment requires that an additive for animal feed be safe for the animal, and under the basic provisions of the Food and Drug Act the product of a diseased animal is deemed adulterated.

We therefore have included in the enclosed draft bill an amendment to permit use of an additive in animal feed under the above-mentioned conditions.

It may aid public understanding of the Delaney proviso and allay unnecessary apprehension regarding it, to touch here on the proviso's operation where its application, under present law and the proposed modification, depends on whether a residue of the chemical additive involved is left in the edible tissue or other food products of an animal. This question may arise in two types of case. In the first, a veterinary drug is directly administered—by injection, implantation, or otherwise—to the animal, instead of being mixed with its feed. In that event, the Delaney proviso can have application only if a residue of the added drug occurs in food products (such as milk or eggs) of the living animal or in some edible portion or product of the animal after slaughter. In the second type of case, the drug is mixed with feed consumed by an animal. In that event, it is necessarily a food additive (since animal feed is food within the meaning of the act), but it will nevertheless be taken out of the Delaney proviso's application by the above-proposed amendment even if it is cancer inciting (at particular feeding levels) in test animals, provided that it satisfies the

above-mentioned requirements as to the absence of adverse effect on the animals for which the feed is intended and as to the absence of any residue in the food products or edible portions of the animal.

In both these instances, where the question of the possibility of a residue is crucial, it is desirable that industry, laboratory technicians, and enforcement officers have a common understanding with the Food and Drug Administration as to the methods of assay that will be recognized by us, and on which we intend to rely, in resolving the question of residue. We have, therefore, in the proposed amendment to the Delaney proviso (and likewise in the proposed modification of the anticancer clause of H.R. 7624) provided that, under the amendment, the assay methods applicable in determining whether there will be a residue shall be those prescribed or approved by us by regulations. This will give reasonable certainty in that regard, although, of course, such regulations may from time to time be changed as new scientific developments demonstrate a need for change. It should be clearly understood that the industry still would have the responsibility of developing adequate analytical methods for detecting residues and furnishing them to the Government with a petition for approval of an additive.

During the hearings on color additives legislation, some witnesses expressed concern because of their fear that the Department intends to press a never-ending search for more and more delicate methods of analysis, so that it may, without regard to scientific reason, rescind permissions granted earlier for use of various additives judged to leave no residues in food. This fear is not justified.

The Department applies sound scientific judgment and the rule of reason in determining the sensitivity and precision required in an analytical procedure used to detect residues of added chemicals—even before an additive is approved. And when it has determined that a given degree of sensitivity and precision is appropriate, based upon sound scientific facts, it has no intention of requiring change in the analytical procedure until new scientific developments clearly demonstrate the need.

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
FOOD AND DRUG ADMINISTRATION,
Washington, D.C., June 2, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: We understand that in the consideration of the pending color additives legislation (H.R. 7624) a question has been raised by the Committee on Interstate and Foreign Commerce as to the position of this Department with respect to the coloring of oleomargarine or margarine.

The Federal Food, Drug, and Cosmetic Act permits safe colors to be used in oleomargarine or margarine with appropriate label declaration. Such use would not promote deception in violation of the act, so long as the margarine is sold in accordance with the oleomargarine amendment, Public Law 459, 81st Congress.

Sincerely yours,

GEO. P. LARRICK,
Commissioner of Food and Drugs.

DEPARTMENT OF AGRICULTURE,
Washington, D.C., August 11, 1959.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.*

DEAR CONGRESSMAN HARRIS: This is in reply to your request of June 11, for a report on H.R. 7624, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

This Department would have no objection to enactment of the proposed legislation. The proposed legislation would enable the Secretary of Health, Education, and Welfare to take a realistic position with respect to the use of colors in food products, many of which are agricultural products.

The bill would enable the Secretary of Health, Education, and Welfare to establish tolerance limitations and other conditions of safe use for all color additives in or on foods, drugs, and cosmetics, in a manner similar to that set forth in the Food Additives Amendment of 1958. Under existing law the said Secretary may not establish tolerance limitations for coal-tar colors. A color additive would be deemed unsafe under the proposed bill if, among other things, it is found after tests which are appropriate for the evaluation of such additives to induce cancer in man or animals. The proposed legislation also contains a provision that its terms should not be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of the Poultry Products Inspection Act. This provision is considered to be consistent with and in no way modifying the provisions of section 902(b) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 392) which exempts meat and meat food products from the terms of that act to the extent of the application thereto of the Meat Inspection Act. Section 18 of the Poultry Products Inspection Act contains an exemption with respect to poultry and poultry products similar to that contained in section 902(b) of the Federal Food, Drug, and Cosmetic Act for meat and meat food products.

We believe that all dyes and colorings for use in or on foods, drugs, and cosmetics should be subject to the same principles presently applicable to food additives. The Secretary of Health, Education, and Welfare should be permitted to establish tolerances for these materials. Enactment of the proposed legislation will avoid such special legislation as that enacted recently permitting the addition of coloring to oranges (Public Law 86-2, approved March 17, 1959).

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

E. L. PETERSON, *Acting Secretary.*

DEPARTMENT OF AGRICULTURE,
Washington, D.C., April 14, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.*

DEAR CONGRESSMAN HARRIS: This is to supplement the Department's statement of March 11 before your committee on H.R. 7624 and S. 2197. These bills proposed amendments to the Federal Food, Drug, and Cosmetic Act concerning color additives.

The Department, in its testimony, favored amending section 101 of Senate bill 2197 by adding before the period on line 10 of page 3 the following language: "or any soil or plant nutrient or any material subject to registration under the Federal Insecticide, Fungicide, and Rodenticide Act."

Dr. Clarkson stated at that time that the language suggested was preliminary and that discussions were being held with representatives of the Department of Health, Education, and Welfare. As a result of these discussions, we are now revising our proposal by recommending that section 101 of S. 2197 be amended by adding a new paragraph 3 on page 3 as follows:

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

I wish to thank you for the courtesies extended Dr. Clarkson in his appearance before your committee.

Sincerely yours,

E. L. PETERSON, *Assistant Secretary.*

DEPARTMENT OF AGRICULTURE,
Washington, D.C., May 16, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives.*

DEAR CONGRESSMAN HARRIS: This is in further reference to the Department's statement of March 11, before your committee on H.R. 7624 and S. 2197, bills which would amend the Federal Food, Drug, and Cosmetic Act relating to color additives. We indicated to the committee at that time that the Department would prefer to delay making any recommendation with reference to the so-called anticancer clause until there had been opportunity to consider the matter further.

We now understand from consultations with representatives of the Department of Health, Education, and Welfare that your committee may wish to consider also the feasibility of amendments to the Food Additives Amendment of 1958, which we understand are being sent to the committee by that Department. Accordingly, we are also commenting on these amendments in this letter.

In the passage of the original Meat Inspection and Food and Drug Acts, the Congress provided for the surveillance of all foods in interstate and foreign commerce.

In the case of meat, a comprehensive inspection system was established with provisions for preclearance in the form of inspection of all carcasses, meats, and meat food products, including approval or rejection of chemicals and other additives. This is done under regulations issued by the Secretary of Agriculture as circumstances and the advance of knowledge require, to assure that the products marked "Inspected and Passed" are sound, healthful, wholesome, fit for human food, and truthfully labeled.

In regard to other foods, covered under the original Food and Drug Act, authority was not given for preclearance, but broad authority was established for action against foods found in interstate or foreign commerce to be in any way adulterated or misbranded.

In recent years, the trend in the Congress has been toward more preclearance in order to serve two purposes: (1) To give greater assurance of safety to the consumer; and (2) to give producers, processors, and distributors more precise guidelines for their operations in order to assure the safety of foods to consumers. Five congressional enactments are in point:

(a) The "new drugs" provisions of the Food, Drug, and Cosmetic Act of 1938 provided for the preclearance of drugs not generally recognized among experts qualified by scientific training and experience as safe for use under the conditions recommended.

(b) The Federal Insecticide, Fungicide, and Rodenticide Act of 1947 provided for USDA preexamination of economic poisons including labeling to insure safety and effectiveness in use.

(c) The "Miller amendment" to the Food, Drug, and Cosmetic Act in 1954 provided more workable procedures for HEW preclearance of pesticide chemicals in or on raw agricultural commodities by authorizing the establishment of tolerances when needed—legal levels—of such chemicals in these products. The directions for use on labels registered by USDA for pesticides are gaged to meet such tolerances in or on the raw agricultural commodities.

(d) The Poultry Products Inspection Act of 1957 provided for extension of the meat inspection type of preclearance to poultry products by USDA.

(e) The Food Additives Amendment of 1958 to the Food, Drug, and Cosmetic Act provided for preclearance of chemicals and other additives to foods.

In each case the Congress provided the mechanism which permits the exercise of scientific and professional judgment in arriving at determinations of safety of use and wholesomeness of the products. These are good provisions. This Department fully supports them. The legislative histories show the necessity for the exercise of such judgment to cope with the complexity of the problems and the rapidly advancing state of knowledge concerning them.

The anticancer clauses contained in the Food Additives Amendment of 1958 and in H.R. 7624 on page 10, lines 11 through 22, are flat prohibitions against the exercise of scientific and professional judgment in the determination of safety. That such a flat prohibition may present problems is well exemplified in the case of selenium, a known carcinogen. Normal amounts (0.1 p.p.m.) in the diet appear to have no measurable effect upon animal health. Sheep on diets with subnormal amounts (0.05 p.p.m. or less) are not thrifty and show abnormalities of the muscular and internal organs. Excessive amounts

(5 p.p.m. and above) in the diet produce poisoning. Here we have a chemical, a carcinogen, a toxicant, which in proper amount is essential to animal health. The law should not prevent proper use of such a chemical as an additive or otherwise.

In view of the above, and since we understand that the Secretary of Health, Education, and Welfare has adequate authority to withhold from use any additive that he is unable to find would be safe in regard to cancer as well as in regard to toxicity and other factors, it is our opinion that the anticancer provisions in lines 11 through 22 on page 10 of H.R. 7624 are unnecessary. This is equally true of the anticancer provisions in the Food Additives Amendment of 1958. We fully agree that the Secretary of Health, Education, and Welfare should withhold from use any additive which in his judgment would be unsafe, but we urge that the decision on safety be left to him rather than being determined by law.

In the event the committee should desire to retain an anticancer clause in the color additive legislation, the following language is submitted for its consideration:

In H.R. 7624, on page 10 at the end of line 22, before the period, insert the following proviso: "*Provided*, That this subsection shall not apply with respect to the use of an additive, if the Secretary finds, upon the basis of evaluation by experts qualified by scientific training and experience, that, under the proposed conditions of use, reasonably certain to be followed in practice, there is no reasonable basis to conclude that such use of the additive will involve a hazard of causing cancer in or resulting in harm to man or animal."

Similar language should be provided for the anticancer clause in the food additives amendment.

We are attaching a copy of the report of the President's Science Advisory Committee released on May 14, 1960, which supports our position on this matter.

If the above proviso is not acceptable and the committee wishes to retain an anticancer clause in H.R. 7624, it is recommended that the following proviso, which is being suggested by the Secretary of Health, Education, and Welfare, be included before the period at the end of section 706(b)(5)(B) (p. 10, line 22, of H.R. 7624): "*Provided*, That clause (i) of this subparagraph (B) shall not apply with respect to the use of a color additive as an ingredient of feed for animals which are raised for food production, if the Secretary finds that, under the conditions of use and feeding specified in proposed labeling and reasonably certain to be followed in practice, such additive will not adversely affect the animals for which such feed is intended, and that no residue of the additive will be found (by methods of examination prescribed or approved by the Secretary by regulations, which regulations shall not be subject to subsection (d)) in any edible portion of such animals after slaughter or in any food yielded by or derived from the living animal."

This proviso contemplated that the Secretary of Health, Education, and Welfare will prescribe or approve methods of examination that would determine whether significant residues of additives remain in any edible portion of slaughtered animals that have consumed such feed or in any food yielded by or derived from the living animal.

Similar language should then be added to the anticancer clause contained in the food additives amendment.

In addition, the Department of Health, Education, and Welfare is proposing a modification of the prior sanction (grandfather) clause contained in section 201(s) of the Food, Drug, and Cosmetic Act as follows:

"The last numbered clause of section 201(s) of the Federal Food, Drug, and Cosmetic Act (which clause is redesignated as clause (4) by section 101(a) of this act) is amended by inserting in such clause, before the period, a colon and the following: '*Provided, That, with respect to any sanction or approval granted pursuant to this Act, this clause shall be inapplicable, and the provisions of this Act (other than this clause) relating to food additives shall apply, to any such previously sanctioned or approved use of a substance if, on the basis of the information then available, the Secretary finds that, for the reasons set forth by him, there is reasonable doubt as to its safety. Except when the Secretary finds that there is an imminent hazard to public health, he shall take such action only in conformity with section 4 of the Administrative Procedure Act if such prior sanction or approval had been made public, and only after sending reasonable notice of his proposed action and the reasons therefor to any person on whose application such prior sanction or approval had been granted and any other person who had been officially advised thereof unless such personal notice is impracticable.*' "

We have no objection to this proposal since it deals only with sanctions or approvals granted by the Secretary of Health, Education, and Welfare under the Food, Drug, and Cosmetic Act and would not affect the authority of this Department or the impact of actions taken by it under programs which it administers.

The Bureau of the Budget advises that there is no objection to the submission of this report.

Sincerely yours,

TRUE D. MORSE, *Acting Secretary.*

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., August 10, 1959.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

MY DEAR MR. CHAIRMAN: This is in reply to your request of June 11, 1959, for a report from the Bureau of the Budget on H.R. 7624, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which additives may be safely used.

H.R. 7624 embodies the proposed legislation submitted to the Congress by the Department of Health, Education, and Welfare to establish safe tolerances for the use of color additives in foods, drugs, and cosmetics. The bill is patterned after the Food Additives Amendment of 1958 in which, after pretesting in accordance with controlled procedures, the amounts and conditions governing the safe use of food additives is established by regulation of the Secretary. Under

the present law regulating the use of color additives, a given additive must be excluded from use if it is found to be harmful under any circumstances, even though it may be quite safe if used in more minimal quantities or under certain specific circumstances.

The general purpose of the bill is to set aside the obsolete provisions now controlling the use of color additives and replace them with provisions which are more realistic and more scientifically sound. Accordingly, the Bureau of the Budget would have no objection to the enactment of H.R. 7624.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

EXECUTIVE OFFICE OF THE PRESIDENT,
BUREAU OF THE BUDGET,
Washington, D.C., April 13, 1960.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives, Washington, D.C.*

MY DEAR MR. CHAIRMAN: This is in reply to your letter of March 30, 1960, regarding your committee's urgent interest in information on the position of the administration on H.R. 7624, the color additive amendment to the Food and Drug Act. You make specific reference to the so-called Delaney amendment.

In earlier testimony on the general subject of the Delaney amendment, the Secretary of Health, Education, and Welfare stated that in the present state of scientific knowledge, and unless otherwise required by law, he would not establish any tolerance for an additive which could enter the human diet if the substance had been found to cause cancer when fed to test animals. Since the Secretary's testimony, this matter has been intensively studied by the executive branch. These studies do not appear to provide the basis for any change at this time in the position expressed by the Secretary. This matter will, of course, be under continuous study, and if additional scientific evidence indicates that further relaxation of the Delaney amendment is desirable, it will of course be proposed.

The Delaney approach is unnecessarily stringent in one respect, however. Where an additive is used in animal food and leaves no residue in the animal after slaughter or in any food product and does not adversely affect the animal, there is no need to apply the proviso. The Secretary of Health, Education, and Welfare will submit language to modify the Delaney amendment in this regard in the near future.

It seems apparent that the Secretary of Health, Education, and Welfare would in any event have the authority to apply the principle of the Delaney amendment to color additives administratively. However, should the Congress desire to explicitly require such action, we see no objection to the procedure. We understand that representatives of the Departments of Health, Education, and Welfare and Agriculture will be appearing further before your committee and can therefore provide the committee with more detailed information on this matter.

Our general comments on H.R. 7624 were presented to your committee in our letter of August 10, 1959.

Sincerely yours,

PHILLIP S. HUGHES,
Assistant Director for Legislative Reference.

DEPARTMENT OF JUSTICE,
August 31, 1959.

HON. OREN HARRIS,
*Chairman, Committee on Interstate and Foreign Commerce,
House of Representatives,
Washington, D.C.*

DEAR MR. CHAIRMAN: This is in response to your request for the views of the Department of Justice concerning the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used."

The general purpose of the bill is to give the Department of Health, Education, and Welfare administrative flexibility and leeway in the administration of the Federal Food, Drug, and Cosmetic Act with reference to all color additives, including coal-tar colors. This would be effected through a number of amendments of provisions of the act, and deleting the present provisions dealing with coal-tar colors and substituting therefor authority to impose controls over color additives.

The subject of this legislation is not a matter for which the Department of Justice has primary responsibility, and accordingly we make no recommendation as to the enactment of the bill.

The Bureau of the Budget has advised that there is no objection to the submission of this report.

Sincerely yours,

LAWRENCE E. WALSH,
Deputy Attorney General.

FEDERAL TRADE COMMISSION,
OFFICE OF THE CHAIRMAN,
Washington, October 9, 1959.

HON. OREN HARRIS,
*Chairman, Interstate and Foreign Commerce Committee,
House of Representatives, Washington, D.C.*

DEAR MR. CHAIRMAN: Reference is made to your request for the Commission's comments on H.R. 7624, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

As indicated by its title, the bill would amend the Federal Food, Drug, and Cosmetic Act with respect to the authority of the Department of Health, Education, and Welfare to regulate the conditions

under which color additives for foods, drugs, and cosmetics may be marketed and used. The proposed legislation, if enacted, would be administered by the Department of Health, Education, and Welfare, and would not directly affect the duties and functions of the Federal Trade Commission.

The opportunity to comment upon the proposed legislation is appreciated. However, in view of the bill's lack of direct affect upon the duties of this agency and the further fact that the Commission has not been immediately concerned with many of the technical and scientific problems involved, there does not appear to be any useful comment which we can offer.

By direction of the Commission.

EARL W. KINTNER, *Chairman*.

NOTE.—Pursuant to regulations, this report was submitted to the Bureau of the Budget on October 7, 1959, and on October 9, 1959, the Commission was advised that there would be no objection to the submission of the report to the committee.

ROBERT M. PARRISH, *Secretary*.



TITLE I—AMENDMENTS TO THE FEDERAL
FOOD, DRUG, AND COSMETIC ACT

DEFINITIONS

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term “food additive”) is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

“(3) a color additive; or”.

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

“(u) The term ‘safe’, as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal.”

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

“(t) (1) The term ‘color additive’ means a material which—

“(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

“(B) when added or applied to a food, drug, or

1 cosmetic, or to the human body or any part thereof, is
 2 capable (alone or through reaction with other sub-
 3 stance) of imparting color thereto;
 4 except that such term does not include any material which
 5 the Secretary, by regulation, determines is used (or intended
 6 to be used) solely for a purpose or purposes other than
 7 coloring.

8 “(2) The term ‘color’ includes black, white, and inter-
 9 mediate ~~grays.~~” *grays.*

10 “(3) *Nothing in subparagraph (1) of this paragraph*
 11 *shall be construed to apply to any pesticide chemical, soil or*
 12 *plant nutrient, or other agricultural chemical solely because of*
 13 *its effect in aiding, retarding, or otherwise affecting, directly*
 14 *or indirectly, the growth or other natural physiological proc-*
 15 *esses of produce of the soil and thereby affecting its color,*
 16 *whether before or after harvest.”*

17 **COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE**
 18 **ADULTERATED OR MISBRANDED FOODS, DRUGS, OR**
 19 **COSMETICS**

20 **Food**

21 **SEC. 102. (a) (1) Clause (2) (A) of section 402 (a),**
 22 **as amended, of such Act (relating to food deemed adulter-**
 23 **ated by reason of unsafe additives) is further amended by**
 24 **striking out the matter within the parentheses and inserting**
 25 **in lieu thereof the following: “other than one which is (i)**

1 a pesticide chemical in or on a raw agricultural commodity;
2 (ii) a food additive; or (iii) a color additive”.

3 (2) Section 402 (c) , as amended, of such Act (relating
4 to food deemed adulterated by reason of uncertified coal-tar
5 color) is amended to read as follows:

6 “(c) If it is, or it bears or contains, a color additive
7 which is unsafe within the meaning of section 706 (a).”

8 (3) Section 403 of such Act (relating to the circum-
9 stances under which food is deemed misbranded) is amended
10 by adding at the end thereof the following new paragraph:

11 “(1) If it is a color additive, unless its packaging and
12 labeling are in conformity with such packaging and labeling
13 requirements, applicable to such color additive, as may be
14 contained in regulations issued under section 706.”

15 **Drugs**

16 (b) (1) Clause (4) of section 501 (a) of such Act
17 (relating to drugs deemed adulterated by reason of uncerti-
18 fied coal tar color) is amended to read as follows: “(4) if
19 (A) it is a drug which bears or contains, for purposes of
20 coloring only, a color additive which is unsafe within the
21 meaning of section 706 (a) , or (B) it is a color additive the
22 intended use of which in or on drugs is for purposes of color-
23 ing only and is unsafe within the meaning of section
24 706 (a).”

25 (2) Section 502 of such Act (relating to the circum-

stances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

“(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.”

Cosmetics

(c) (1) Section 601 (e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

“(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706 (a).”

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

“(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which,

1 with respect to their use for cosmetics, are marketed and
2 intended for use only in or on hair dyes (as defined in the
3 last sentence of section 601 (a)).”

4 REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR
5 FOODS, DRUGS, AND COSMETICS

6 SEC. 103. (a) Such Act is further amended by—

7 (1) repealing subsection (b) of section 406 and
8 striking out the subsection designation “(a)” after “SEC.
9 406.” in such section;

10 (2) repealing section 504;

11 (3) repealing section 604; and

12 (4) amending section 701 (e) by (A) striking
13 out “406 (a) or (b)” and inserting in lieu thereof
14 “406”; (B) striking out “504, or 604,”; and (C) in-
15 serting the word “or” after “501 (b),”.

16 (b) Section 706 of such Act is amended to read as
17 follows:

18 “LISTING AND CERTIFICATION OF COLOR ADDITIVES
19 FOR FOODS, DRUGS, AND COSMETICS

20 “When Color Additives Deemed Unsafe

21 “SEC. 706. (a) A color additive shall, with respect to
22 any particular use (for which it is being used or intended
23 to be used or is represented as suitable) in or on food or
24 drugs or cosmetics, be deemed unsafe for the purposes of

1 the application of section 402 (c), section 501 (a) (4), or
2 section 601 (e), as the case may be, unless—

3 “(1) (A) there is in effect, and such additive and
4 such use are in conformity with, a regulation issued under
5 subsection (b) of this section listing such additive for
6 such use, including any provision of such regulation pre-
7 scribing the conditions under which such additive may
8 be safely used, and (B) such additive either (i) is
9 from a batch certified, in accordance with regulations
10 issued pursuant to subsection (c), for such use, or (ii)
11 has, with respect to such use, been exempted by the Sec-
12 retary from the requirement of certification; or

13 “(2) such additive and such use thereof conform
14 to the terms of an exemption which is in effect pursuant
15 to subsection (f) of this section.

16 While there are in effect regulations under subsections (b)
17 and (c) of this section relating to a color additive or an ex-
18 emption pursuant to subsection (f) with respect to such
19 additive, an article shall not, by reason of bearing or contain-
20 ing such additive in all respects in accordance with such reg-
21 ulations or such exemption, be considered adulterated within
22 the meaning of clause (1) of section 402 (a) if such article
23 is a food, or within the meaning of section 601 (a) if such

1 article is a cosmetic other than a hair dye (as defined in the
2 last sentence of section 601 (a)).

3 "Listing of Colors

4 "(b) (1) The Secretary shall, by regulation, provide
5 for separately listing color additives for use in or on food,
6 color additives for use in or on drugs, and color additives for
7 use in or on cosmetics, if and to the extent that such addi-
8 tives are suitable and safe for any such use when employed
9 in accordance with such regulations.

10 "(2) (A) Such regulations may list any color additive
11 for use generally in or on food, or in or on drugs, or in or on
12 cosmetics, if the Secretary finds that such additive is suitable
13 and may safely be employed for such general use.

14 "(B) If the data before the Secretary do not establish
15 that the additive satisfies the requirements for listing such
16 additive on the applicable list pursuant to subparagraph (A)
17 of this paragraph, or if the proposal is for listing such addi-
18 tive for a more limited use or uses, such regulations may list
19 such additive only for any more limited use or uses for which
20 it is suitable and may safely be employed.

21 "(3) Such regulations shall, to the extent deemed
22 necessary by the Secretary to assure the safety of the use or
23 uses for which a particular color additive is listed, prescribe
24 the conditions under which such additive may be safely
25 employed for such use or uses (including, but not limited to,

specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

~~“(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish—~~

~~“(A) that such use, under the conditions of use to be specified in the regulations, will be safe;~~

~~“(B) that practicable methods of analysis exist for determining the quantity of the pure dye and all intermediates and other impurities contained in such color additive; and~~

~~“(C) that practicable methods exist for determining the identity and quantity (i) of such additive in or on any article of food, drug, or cosmetic, and (ii) of any substance formed in or on such article because of the use of such additive.~~

“(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified

1 *in the regulations, will be safe: Provided, however, That a*
 2 *color additive shall be deemed to be suitable and safe for the*
 3 *purpose of listing under this subsection for use generally*
 4 *in or on food, while there is in effect a published finding*
 5 *of the Secretary declaring such substance exempt from the*
 6 *term 'food additive' because of its being generally recognized*
 7 *by qualified experts as safe for its intended use, as provided*
 8 *in section 201(s).*

9 “(5) (A) In determining, for the purposes of this sec-
 10 tion, whether a proposed use of a color additive is safe, the
 11 Secretary shall consider, among other relevant factors—

12 “(i) the probable consumption of, or other relevant
 13 exposure from, the additive and of any substance formed
 14 in or on food, drugs, or cosmetics because of the use of
 15 the additive,

16 “(ii) the cumulative effect, if any, of such additive
 17 in the diet of man or animals, taking into account the
 18 same or any chemically or pharmacologically related sub-
 19 stance or substances in such diet; and

20 “(iii) safety factors which, in the opinion of ex-
 21 perts qualified by scientific training and experience to
 22 evaluate the safety of color additives for the use or uses
 23 for which the additive is proposed to be listed, are gen-
 24 erally recognized as appropriate for the use of animal
 25 experimentation ~~data~~ data; and

1 “(iv) the availability of any needed practicable
2 *methods of analysis for determining the identity and*
3 *quantity of (I) the pure dye and all intermediates and*
4 *other impurities contained in such color additive, (II)*
5 *such additive in or on any article of food, drug, or cos-*
6 *metic, and (III) any substance formed in or on such*
7 *article because of the use of such additive.*

8 “(B) A color additive (i) shall be deemed unsafe, and
9 shall not be listed, for any use which will or may result in
10 ingestion of all or part of such additive, if the additive is found
11 *by the Secretary* to induce cancer when ingested by man or
12 animal, or if it is found *by the Secretary*, after tests which are
13 appropriate for the evaluation of the safety of additives for
14 use in food, to induce cancer in man or animal, and (ii)
15 shall be deemed unsafe, and shall not be listed, for any use
16 which will not result in ingestion of any part of such additive,
17 if, after tests which are appropriate for the evaluation of the
18 safety of additives for such use, or after other relevant ex-
19 posure of man or animal to such additive, it is found *by the*
20 *Secretary* to induce cancer in man or animal.

21 “(C)(i) *In any proceeding for the issuance, amend-*
22 *ment, or repeal of a regulation listing a color additive,*
23 *whether commenced by a proposal of the Secretary on his own*
24 *initiative or by a proposal contained in a petition, the peti-*
25 *tioner, or any other person who will be adversely affected*

1 by such proposal or by the Secretary's order issued in ac-
2 cordance with paragraph (1) of section 701(e)) if placed
3 in effect, may request, within the time specified in this sub-
4 paragraph, that the petition or order thereon, or the Secre-
5 tary's proposal, be referred to an advisory committee for a
6 report and recommendations with respect to any matter aris-
7 ing under subparagraph (B) of this paragraph, which is in-
8 volved in such proposal or order and which requires the
9 exercise of scientific judgment. Upon such request, or if the
10 Secretary within such time deems such a referral necessary,
11 the Secretary shall forthwith appoint an advisory committee
12 under subparagraph (D) of this paragraph and shall refer
13 to it, together with all the data before him, such matter arising
14 under subparagraph (B) for study thereof and for a report
15 and recommendations on such matter. A person who has
16 filed a petition or who has requested the referral of a matter
17 to an advisory committee pursuant to this subparagraph
18 (C), as well as representatives of the Department of Health,
19 Education, and Welfare, shall have the right to consult with
20 such advisory committee in connection with the matter re-
21 ferred to it. The request for referral under this subpara-
22 graph, or the Secretary's referral on his own initiative, may
23 be made at any time before, or within thirty days after, publi-
24 cation of an order of the Secretary acting upon the petition
25 or proposal.

1 “(ii) Within sixty days after the date of such referral,
2 or within an additional thirty days if the committee deems
3 such additional time necessary, the committee shall, after in-
4 dependent study of the data furnished to it by the Secretary
5 and other data before it, certify to the Secretary a report
6 and recommendations, together with all underlying data and
7 a statement of the reasons or basis for the recommendations.
8 A copy of the foregoing shall be promptly supplied by the
9 Secretary to any person who has filed a petition, or who has
10 requested such referral to the advisory committee. Within
11 thirty days after such certification, and after giving due
12 consideration to all data then before him, including such re-
13 port, recommendations, underlying data, and statement, and
14 to any prior order issued by him in connection with such mat-
15 ter, the Secretary shall by order confirm or modify any order
16 theretofore issued or, if no such prior order has been issued,
17 shall by order act upon the petition or other proposal.

18 “(iii) Where—

19 “(I) by reason of subparagraph (B) of this para-
20 graph, the Secretary has initiated a proposal to remove
21 from listing a color additive previously listed pursuant
22 to this section; and

23 “(II) a request has been made for referral of such
24 proposal to an advisory committee;

1 the Secretary may not act by order on such proposal until
2 the advisory committee has made a report and recommenda-
3 tions to him under clause (ii) of this subparagraph and he
4 has considered such recommendations, unless the Secretary
5 finds that emergency conditions exist necessitating the issuance
6 of an order notwithstanding this clause.

7 “(D) The advisory committee referred to in subpara-
8 graph (C) of this paragraph shall be composed of experts
9 selected by the National Academy of Sciences, qualified in
10 the subject matter referred to the committee and of adequately
11 diversified professional background, except that in the event
12 of the inability or refusal of the National Academy of Sciences
13 to act, the Secretary shall select the members of the committee.
14 The size of the committee shall be determined by the Secre-
15 tary. Members of an advisory committee shall receive as
16 compensation for their services a reasonable per diem, which
17 the Secretary shall by rules and regulations prescribe, for
18 time actually spent in the work of the committee, and shall in
19 addition be reimbursed for their necessary traveling and sub-
20 sistence expenses while so serving away from their places of
21 residence. The members shall not be subject to any other
22 provisions of law regarding the appointment and compensa-
23 tion of employees of the United States. The Secretary shall
24 furnish the committee with adequate clerical and other as-

1 *sistance, and shall by rules and regulations prescribe the*
2 *procedure to be followed by the committee.*

3 “(6) The Secretary shall not list a color additive under
4 this subsection for a proposed use if the data before him
5 show that such proposed use would promote deception of
6 the consumer in violation of this Act or would otherwise
7 result in misbranding or adulteration within the meaning
8 of this Act.

9 “(7) If, in the judgment of the Secretary, a tolerance
10 limitation is required in order to assure that a proposed use
11 of a color additive will be safe, the Secretary—

12 “(A) shall not list the additive for such use if he
13 finds that the data before him do not establish that
14 such additive, if used within a safe tolerance limita-
15 tion, would achieve the intended physical or other
16 technical effect; and

17 “(B) shall not fix such tolerance limitation at a
18 level higher than he finds to be reasonably required
19 to accomplish the intended physical or other technical
20 effect.

21 “(8) If, having regard to the aggregate quantity of
22 color additive likely to be consumed in the diet or to be
23 applied to the human body, the Secretary finds that the
24 data before him fail to show that it would be safe and other-

1 wise permissible to list a color additive (or pharmacolog-
2 ically related color additives) for all the uses proposed there-
3 for and at the levels of concentration proposed, the Secretary
4 shall, in determining for which use or uses such additive
5 (or such related additives) shall be or remain listed, or
6 how the aggregate allowable safe tolerance for such addi-
7 tive or additives shall be allocated by him among the uses
8 under consideration, take into account, among other rele-
9 vant factors (and subject to the paramount criterion of
10 safety), (A) the relative marketability of the articles in-
11 volved as affected by the proposed uses of the color additive
12 (or of such related additives) in or on such articles, and
13 the relative dependence of the industries concerned on such
14 uses; (B) the relative aggregate amounts of such color
15 additive which he estimates would be consumed in the diet
16 or applied to the human body by reason of the various uses
17 and levels of concentration proposed; and (C) the avail-
18 ability, if any, of other color additives suitable and safe for
19 one or more of the uses proposed.

20 "Certification of Colors

21 "(c) The Secretary shall further, by regulation, provide
22 (1) for the certification, with safe diluents or without dilu-
23 ents, of batches of color additives listed pursuant to subsec-
24 tion (b) and conforming to the requirements for such addi-
25 tives established by regulations under such subsection and

1 this subsection, and (2) for exemption from the requirement
 2 of certification in the case of any such additive, or any listing
 3 or use thereof, for which he finds such requirement not to be
 4 necessary in the interest of the protection of the public
 5 health: *Provided, That, with respect to any use in or*
 6 *on food for which a listed color additive is deemed to be*
 7 *safe by reason of the proviso to paragraph (4) of subsection*
 8 *(b), the requirement of certification shall be deemed not to*
 9 *be necessary in the interest of public health protection.*

10 “Procedure for Issuance, Amendment, or Repeal of Regula-
 11 tions

12 “(d) The provisions of section 701 (e), (f), and (g)
 13 of this Act shall, *subject to the provisions of subparagraph*
 14 *(C) of subsection (b)(5) of this section*, apply to and in
 15 all respects govern proceedings for the issuance, amend-
 16 ment, or repeal of regulations under subsections ~~(b)~~, ~~(e)~~,
 17 ~~or (e)~~ subsection (b) or (c) of this section (including judi-
 18 cial review of the Secretary’s action in such proceedings)
 19 and the admissibility of transcripts of the record of such
 20 proceedings in other proceedings, except that—

21 “(1) *if the proceeding is commenced by the filing of*
 22 *a petition, notice of the proposal made by the petition*
 23 *shall be published in general terms by the Secretary*
 24 *within thirty days after such filing, and the Secretary’s*

1 *order (required by paragraph (1) of section 701(e))*
2 *acting upon such proposal shall, in the absence of prior*
3 *referral (or request for referral) to an advisory com-*
4 *mittee, be issued within ninety days after the date of such*
5 *filing, except that the Secretary may (prior to such*
6 *ninetieth day), by written notice to the petitioner, ex-*
7 *tend such ninety-day period to such time (not more than*
8 *one hundred and eighty days after the date of filing of the*
9 *petition) as the Secretary deems necessary to enable him*
10 *to study and investigate the petition;*

11 *“(2) any report, recommendations, underlying data,*
12 *and reasons certified to the Secretary by an advisory*
13 *committee appointed pursuant to subparagraph (D)*
14 *of subsection (b)(5) of this section, shall be made a part*
15 *of the record of any hearing if relevant and material,*
16 *subject to the provisions of section 7(c) of the Adminis-*
17 *trative Procedure Act (5 U.S.C., sec. 1006(c)). The*
18 *advisory committee shall designate a member to appear*
19 *and testify at any such hearing with respect to the report*
20 *and recommendations of such committee upon request of*
21 *the Secretary, the petitioner, or the officer conducting*
22 *the hearing, but this shall not preclude any other member*
23 *of the advisory committee from appearing and testifying*
24 *at such hearing;*

1 “~~(1)~~ (3) the Secretary’s order after public hearing
2 (acting upon objections filed to an order made prior
3 to hearing) shall be subject to the requirements of sec-
4 tion 409 (f) (2)’; and

5 “~~(2)~~ (4) the scope of judicial review of such order
6 shall be in accordance with the third sentence of para-
7 graph (2), and with the provisions of paragraph (3),
8 of section 409(g).

9 “Fees

10 “(e) The admitting to listing and certification of color
11 additives, in accordance with regulations prescribed under
12 this Act, shall be performed only upon payment of such
13 fees, which shall be specified in such regulations, as may be
14 necessary to provide, maintain, and equip an adequate serv-
15 ice for such purposes.

16 “Exemptions

17 “(f) The Secretary shall by regulation (issued without
18 regard to subsection (d)) provide for exempting from the
19 requirements of this section any color additive or any spe-
20 cific type of use thereof, and any article of food, drug, or
21 cosmetic bearing or containing such additive, intended solely
22 for investigational use by qualified experts when in his
23 opinion such exemption is consistent with the public health.”

1 CONFIDENTIALITY OF TRADE SECRETS

2 SEC. 104. Section 301 (j), as amended, of such Act,
3 prohibiting disclosure of trade secrets, is amended by strik-
4 ing out “or 704” and inserting in lieu thereof “704, or 706”.

5 CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

6 SEC. 105. Such Act is further amended by—

7 (a) striking out, in section 301 (i) thereof (relating
8 to forgery or unauthorized use of certain identification
9 devices), “404, 406 (b), 504, 506, 507, or 604”, and
10 inserting in lieu thereof “404, 506, 507, or 706”;

11 (b) (1) striking out, in clause (3) of section
12 303 (c) (relating to color manufacturer’s guarantee),
13 the word “coal-tar” wherever it appears in such clause,
14 and (2) inserting after the word “color”, wherever it
15 appears in such clause, the word “additive”; and

16 (c) striking out “harmless coloring” in section
17 402 (d) (relating to nonnutritive substances in con-
18 fectionery) and inserting in lieu thereof “authorized
19 coloring”.

20 TITLE II—EFFECTIVE DATE, TRANSITIONAL
21 PROVISIONS, AND EFFECT ON OTHER LAWS

22 DEFINITIONS

23 SEC. 201. As used in this title, the term “basic Act”
24 means the Federal Food, Drug, and Cosmetic Act; the term
25 “enactment date” means the date of enactment of this Act;

1 and other terms, insofar as also used in the basic Act
2 (whether before or after enactment of this Act) shall have
3 the same meaning as they have, or had when in effect, under
4 the basic Act.

5 EFFECTIVE DATE

6 SEC. 202. This Act shall, subject to the provisions of
7 section 203, take effect on the enactment date.

8 PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED 9 COLORS

10 SEC. 203. (a) (1) The purpose of this section is to
11 make possible, on an interim basis for a reasonable period,
12 through provisional listings, the use of commercially estab-
13 lished color additives to the extent consistent with the public
14 health, pending the completion of the scientific investiga-
15 tions needed as a basis for making determinations as to list-
16 ing of such additives under the basic Act as amended by this
17 Act. A provisional listing (including a deemed provisional
18 listing) of a color additive under this section for any use
19 shall, unless sooner terminated or expiring under the pro-
20 visions of this section, expire (A) on the closing date (as
21 defined in paragraph (2) of this subsection) or (B) on the
22 effective date of a listing of such additive for such use under
23 section 706 of the basic Act, whichever date first occurs.

24 (2) For the purposes of this section, the term "closing
25 date" means (A) the last day of the two and one-half year

1 period beginning on the enactment date or (B), with respect
2 to a particular provisional listing (or deemed provisional
3 listing) of a color additive or use thereof, such later closing
4 date as the Secretary may from time to time establish pursu-
5 ant to the authority of this paragraph. The Secretary may
6 by regulation, upon application of an interested person or on
7 his own initiative, from time to time postpone the original
8 closing date with respect to a provisional listing (or deemed
9 provisional listing) under this section of a specified color ad-
10 ditive, or of a specified use or uses of such additive, for such
11 period or periods as he finds necessary to carry out the pur-
12 pose of this section, if in the Secretary's judgment such ac-
13 tion is consistent with the objective of carrying to completion
14 in good faith, as soon as reasonably practicable, the scientific
15 investigations necessary for making a determination as to
16 listing such additive, or such specified use or uses thereof,
17 under section 706 of the basic Act. The Secretary may ter-
18 minate a postponement of the closing date at any time if he
19 finds that such postponement should not have been granted,
20 or that by reason of a change in circumstances the basis for
21 such postponement no longer exists, or that there has been
22 a failure to comply with a requirement for submission of
23 progress reports or with other conditions attached to such
24 postponement.

25 (b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406 (b) , 504, or 604, or under the third proviso of section 402 (c) , of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A) , on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d) , shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406 (b) , 504, or 604 of the basic Act prior to the enactment date, although

1 such color was no longer listed and certifiable for such use
2 under such sections on the day preceding the enactment date.
3 Such provisional listing shall take effect on the date of pub-
4 lication.

5 (d) (1) The Secretary shall, by regulations issued or
6 amended from time to time under this section—

7 (A) insofar as practicable promulgate and keep
8 current a list or lists of the color additives, and of the
9 particular uses thereof, which he finds are deemed pro-
10 visionally listed under subsection (b), and the presence
11 of a color additive on such a list with respect to a
12 particular use shall, in any proceeding under the basic
13 Act, be conclusive evidence that such provisional listing
14 is in effect;

15 (B) provide for the provisional listing of the color
16 additives and particular uses thereof specified in sub-
17 section (c);

18 (C) provide, with respect to particular uses for
19 which color additives are or are deemed to be pro-
20 visionally listed, such temporary tolerance limitations
21 (including such limitations at zero level) and other
22 conditions of use and labeling or packaging require-
23 ments, if any, as in his judgment are necessary to pro-
24 tect the public health pending listing under section 706
25 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) ~~Regulations~~ *Except as provided in subparagraph (C) of this paragraph, regulations* under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706 (e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. *Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pur-*

1 suant to section 706 of the basic Act, shall be deemed to be
2 regulations under such section 706 as amended by this Act,
3 and appropriations of fees (and advance deposits) available
4 for the purposes specified in such section 706 as in effect prior
5 to the enactment date shall be available for the purposes speci-
6 fied in such section 706 as so amended.

7 (B) If the Secretary, by regulation—

8 (i) has terminated a provisional listing (or deemed
9 provisional listing) of a color additive or particular use
10 thereof pursuant to paragraph (1)(E) of this sub-
11 section; or

12 (ii) has, pursuant to paragraph (1)(C) or para-
13 graph (3) of this subsection, initially established or
14 rendered more restrictive a tolerance limitation or other
15 restriction or requirement with respect to a provisional
16 listing (or deemed provisional listing) which listing had
17 become effective prior to such action,

18 any person adversely affected by such action may, prior to
19 the expiration of the period specified in clause (A) of sub-
20 section (a)(2) of this section, file with the Secretary a peti-
21 tion for amendment of such regulation so as to revoke or
22 modify such action of the Secretary, but the filing of such
23 petition shall not operate to stay or suspend the effectiveness
24 of such action. Such petition shall, in accordance with regu-
25 lations, set forth the proposed amendment and shall contain

1 data (or refer to data which are before the Secretary or of
2 which he will take official notice), which show that the revoca-
3 tion or modification proposed is consistent with the protection
4 of the public health. The Secretary shall, after publishing
5 such proposal and affording all interested persons an oppor-
6 tunity to present their views thereon orally or in writing, act
7 upon such proposal by published order.

8 (C) Any person adversely affected by an order
9 entered under subparagraph (B) of this paragraph may,
10 within thirty days after its publication, file objections
11 thereto with the Secretary, specifying with particularity the
12 provisions of the order deemed objectionable, stating reason-
13 able grounds for such objections, and requesting a public
14 hearing upon such objections. The Secretary shall hold a
15 public hearing on such objections and shall, on the basis of
16 the evidence adduced at such hearing, act on such objections
17 by published order. Such order may reinstate a terminated
18 provisional listing, or increase or dispense with a previously
19 established temporary tolerance limitation, or make less re-
20 strictive any other limitation established by him under para-
21 graph (1) or (3) of this subsection, only if in his judgment
22 the evidence so adduced shows that such action will be con-
23 sistent with the protection of the public health. An order
24 entered under this subparagraph shall be subject to judicial
25 review in accordance with section 701(f) of the basic Act

1 *except that the findings and order of the Secretary shall be*
2 *sustained only if based upon a fair evaluation of the entire*
3 *record at such hearing. No stay or suspension of such order*
4 *shall be ordered by the court pending conclusion of such*
5 *judicial review.*

6 ~~(B)~~ (D) On and after the enactment date, regulations,
7 provisional listings, and certifications (or exemptions from
8 certification) in effect under this section shall, for the purpose
9 of determining whether an article is adulterated or mis-
10 branded within the meaning of the basic Act by reason of
11 its being, bearing, or containing a color additive, have the
12 same effect as would regulations, listings, and certifications
13 (or exemptions from certification) under section 706 of the
14 basic Act. A regulation, provisional listing or termination
15 thereof, tolerance limitation, or certification or exemption
16 therefrom, under this section shall not be the basis for any
17 presumption or inference in any proceeding under section
18 706 (b) or (c) of the basic Act.

19 (3) For the purpose of enabling the Secretary to carry
20 out his functions under ~~paragraph (1)(A) and (C)~~ *para-*
21 *graphs (1)(A) and (C) of this subsection* with respect to
22 color additives deemed provisionally listed, he shall, as soon
23 as practicable after enactment of this Act, afford by public
24 notice a reasonable opportunity to interested persons to sub-
25 mit data relevant thereto. If the data so submitted or other-

1 wise before him do not, in his judgment, establish a reliable
2 basis for including such a color additive or particular use or
3 uses thereof in a list or lists promulgated under paragraph
4 (1) (A), or for determining the prevailing level or levels of
5 use thereof prior to the enactment date with a view to pre-
6 scribing a temporary tolerance or tolerances for such use or
7 uses under paragraph (1) (C), the Secretary shall establish
8 a temporary tolerance limitation at zero level for such use
9 or uses until such time as he finds that it would not be in-
10 consistent with the protection of the public health to increase
11 or dispense with such temporary tolerance limitation.

12 EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS

13 INSPECTION ACTS

14 SEC. 204. Nothing in this Act shall be construed to ex-
15 empt any meat or meat food ~~product~~ *product*, *poultry or*
16 *poultry product*, or any person from any requirement im-
17 posed by or pursuant to the Meat Inspection Act of March
18 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C.
19 71 and the following), or the Poultry Products Inspection
20 Act (21 U.S.C. 451 and the following).

A BILL

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

By Mr. HARRIS

JUNE 9, 1959

Referred to the Committee on Interstate and Foreign
Commerce

JUNE 7, 1960

Reported with amendments, committed to the Committee of the Whole House on the State of the Union, and ordered to be printed

House - June 14, 1960

The Rules Committee reported a resolution for consideration of H. R. 7624, to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. p. 11701

4. RECREATION. The Public Works Committee reported with amendment H. R. 900, to provide that 75% of all moneys derived by the U. S. from certain recreation activities in connection with lands acquired for flood control and other purposes shall be paid to the State (H. Rept. 1821). p. 11700

The Public Works Committee reported without amendment H. R. 12539, to authorize the Secretary of the Army, with the consent of Congress, to acquire lands and to establish facilities necessary for recreational purposes in connection with reservoir projects constructed with Federal funds (H. Rept. 1862). p. 11701

5. EDUCATION. The Agriculture Committee reported without amendment H. R. 10876, to increase the appropriation authorization for resident teaching grants to land-grant institutions (H. Rept. 1854). p. 11700

6. PUBLIC DEBT. The Banking and Currency Committee reported without amendment H. R. 12346, to extend for two years the authority of the Federal Reserve banks to purchase U. S. obligations directly from the Treasury (H. Rept. 1825). p. 11700

7. WILDLIFE. The Judiciary Committee reported with amendment H. R. 10598, to clarify certain provisions of the Criminal Code relating to the importation or shipment of injurious mammals, birds, amphibians, fish, and reptiles, and relating to the transportation or receipt of wild mammals or birds taken in violation of State, National or foreign laws (H. Rept. 1823). pp. 11700-1

8. LANDS. Received from the Defense Department proposed legislation to provide for the withdrawal from the public domain of lands in the Ladd-Eielson, Big Delta, and Granite Creek areas of Alaska; to Interior and Insular Affairs Committee. p. 11700

9. WATER DEVELOPMENT. The Public Works Committee reported without amendment H. R. 12564, to authorize multiple-purpose development at Victory Reservoir site, Vt. (H. Rept. 1830). p. 11700

10. PERSONNEL. A subcommittee of the Post Office and Civil Service Committee voted to report to the full committee H. R. 12336, to amend the Classification Act of 1949 with respect to the preservation of basic compensation in downgrading actions. p. D550

11. MUTUAL SECURITY. Rep. Yates criticized the Appropriations Committee's action against the use of funds to carry out the provisions of the Mutual Security Act relating to the U. S. contribution toward settlement of the Indus River Basin controversy between India and Pakistan. p. 11688

Rep. Conte agreed with Rep. Yates' criticism and stated that he would offer an amendment to "delete this limitation." pp. 11694-6

12. FOREIGN TRADE. Rep. Bray urged support for a resolution which would express the sense of Congress that no further tariff reductions be granted by the U. S. in forthcoming tariff negotiations. p. 11689

Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF
BUDGET AND FINANCE

(For Department
Staff Only)

Issued June 15, 1960

For actions of June 14, 1960

86th-2d, No. 108

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HIGHLIGHTS: House received conference report on agricultural appropriation bill. Senate committees reported: Housing bill; Labor-NEW appropriation bill; bill to extend Defense Production Act. House Rules Committee cleared bill for use of color additives in food. Sen. Aiken praised Foreign Agricultural Service. Rep. Hoeven introduced and discussed sugar bill.

HOUSE

1. **AGRICULTURAL APPROPRIATION BILL, 1961.** Received the conference report on this bill, H. R. 12117 (H. Rept. 1863) (pp. 11693-700, 11701). Attached to this digest is a copy of the conference report and a summary of the action of the conferees.
2. **PERSONNEL.** The Judiciary Committee reported without amendment H. R. 12620, to provide for the defense of suits against Federal employees arising out of their operation of motor vehicles in the scope of their employment (H. Rept. 1863) (p. 11701). The "Daily Digest" states that this bill is a clean bill reported by the committee to overcome the objections contained in the President's veto of H. R. 7577. p. D550
3. **COLOR ADDITIVES; HAZARDOUS SUBSTANCES.** The Interstate and Foreign Commerce Committee reported with amendment S. 1283, to regulate the interstate distribution and sale of packages of hazardous substances intended or suitable for household use (H. Rept. 1861). p. 11701

CONSIDERATION OF H.R. 7624

JUNE 14, 1960.—Referred to the House Calendar and ordered to be printed

Mr. DELANEY, from the Committee on Rules, submitted the following

R E P O R T

[To accompany H. Res. 559]

The Committee on Rules, having had under consideration House Resolution 559, report the same to the House with the recommendation that the resolution do pass.



House Calendar No. 247

86TH CONGRESS
2D SESSION

H. RES. 559

[Report No. 1867]

IN THE HOUSE OF REPRESENTATIVES

JUNE 14, 1960

Mr. DELANEY, from the Committee on Rules, reported the following resolution;
which was referred to the House Calendar and ordered to be printed

RESOLUTION

1 *Resolved*, That upon the adoption of this resolution it
2 shall be in order to move that the House resolve itself
3 into the Committee of the Whole House on the State of
4 the Union for the consideration of the bill (H.R. 7624)
5 to protect the public health by amending the Federal Food,
6 Drug, and Cosmetic Act so as to authorize the use of
7 suitable color additives in or on foods, drugs, and cosmetics,
8 in accordance with regulations prescribing the conditions
9 (including maximum tolerances) under which such addi-
10 tives may be safely used. After general debate, which shall
11 be confined to the bill, and shall continue not to exceed
12 two hours, to be equally divided and controlled by the

1 chairman and ranking minority member of the Committee
2 on Interstate and Foreign Commerce, the bill shall be read
3 for amendment under the five-minute rule. At the con-
4 clusion of the consideration of the bill for amendment, the
5 Committee shall rise and report the bill to the House with
6 such amendments as may have been adopted, and the
7 previous question shall be considered as ordered on the bill
8 and amendments thereto to final passage without intervening
9 motion except one motion to recommit.

86TH CONGRESS
2D Session

H. RES. 559

[Report No. 1867]

RESOLUTION

Providing for the consideration of H.R. 7624, a bill to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

By Mr. DELANEY

JUNE 14, 1960

Referred to the House Calendar and ordered to be printed

June 25, 1960

22. RECREATION FACILITIES. The Public Works Committee reported with amendment S. 3260, to authorize the Secretary of the Army to modify certain leases entered into for the provisions of recreation facilities in reservoir areas (S. Rept. 1724). p. 13095
23. FOREST ROADS. The Public Works Committee reported with amendment H. R. 10495, to authorize appropriations for the fiscal years 1962 and 1963 for the construction of highways, including authorization for the construction of forest highways and forest development roads and trails (S. Rept. 1725). p. 13095
24. RYUKYU ISLANDS. The Armed Services Committee reported with amendments H. R. 1157, to provide for promotion of the economic and social development in the Ryukyu Islands (S. Rept. 1738). p. 13096
25. FINANCE; U. S. OBLIGATIONS. The Banking and Currency Committee reported without amendment S. 3702, to extend for 2 years the authority of Federal Reserve Banks to purchase U. S. obligations directly from the Treasury (S. Rept. 1739). p. 13096
26. HAWAII. The Interior and Insular Affairs Committee reported with amendments H. R. 11602, to amend certain laws of the U. S. in light of the admission of Hawaii into the Union (S. Rept. 1681). p. 13095
27. LANDS. The Interior and Insular Affairs Committee reported with amendment S. 2959, to clarify the right of States to select certain public lands subject to any outstanding mineral lease or permit (S. Rept. 1726); and with amendment S. 3212, to direct the Secretary of the Interior to convey certain public lands in Nevada to the county of Mineral (S. Rept. 1727). p. 13095
Received from the Defense Department a proposed bill to provide for the withdrawal of certain public lands 40 miles east of Fairbanks, Alaska, for use by the Army for a Nike range; to Interior and Insular Affairs Committee. p. 13094
28. TRANSPORTATION. The Interstate and Foreign Commerce Committee reported with amendments H. R. 5068, to amend the Shipping Act of 1916 so as to provide for licensing of independent foreign freight forwarders (S. Rept. 1682). p. 13095
29. MILITARY CONSTRUCTION APPROPRIATION BILL, 1961. The Appropriations Committee reported with amendments this bill, H. R. 12231 (S. Rept. 1684). p. 13095
30. TRADEMARKS. The Judiciary Committee reported with amendments S. 2429, to modify the laws relating to the registration and protection of trademarks used in commerce and to carry out provisions of international conventions (S. Rept. 1685). p. 13095
31. PUBLIC WORKS. The Judiciary Committee reported without amendment S. J. Res. 202, providing for the designation of the week commencing Oct. 2, 1960, as National Public Works Week (S. Rept. 1687). p. 13095
32. PROPERTY. The Public Works Committee reported without amendment H. R. 11522, to permit certain real property of the U. S. to be conveyed to States, municipalities, and other political subdivisions for highway purposes (S. Rept. 1722). p. 13095
33. SALINE WATER. Passed as reported S. 3557, to extend and expand the saline water conversion program of the Department of the Interior. pp. 13142-5

34. WATER RESOURCES; INTERNATIONAL DAM. Passed as reported H. R. 12263, to authorize conclusion of an agreement for the joint construction by the U. S. and Mexico of a major international storage dam on the Rio Grande. pp. 13145-6
35. EDUCATION; LAND-GRANT COLLEGES. Passed without amendment S. 3450, to amend section 22 (relating to the endowment and support of colleges of agriculture and mechanic arts) of the Act of June 29, 1935, to increase the authorized appropriation for resident teaching grants to land-grant institutions. pp. 13154-6
36. SMALL BUSINESS. The Banking and Currency Committee voted to report (but did not actually report) S. 3689, to amend the Small Business Act so as to assure small business a share of defense contracts and to establish a system of grants for research and counseling of small business. p. D607
37. MIGRATORY FARM LABOR. Subcommittees of the Labor and Public Welfare Committee approved for full committee consideration the following bills: p. D608
S. 2864, with amendment, to provide Federal payments to assist in providing improved educational opportunities for children of migrant agricultural workers;
S. 2865, to provide Federal grants for adult education for migrant agricultural workers;
S. 1778, (amended version), to provide for the registration of crew leaders in interstate agricultural employment;
S. 2498 (amended version), to provide for the registration of contracts of migrant agricultural workers.
38. HOUSING. Sen. Clark inserted an editorial, "Housing Crazy Quilt," and his letter commenting on the editorial, discussing proposed housing legislation, including the VA direct and guaranteed housing programs. pp. 13107-8
39. NATURAL RESOURCES. Sen. Kennedy urged greater development of our natural resources, including the national forests, water resources, and mineral resources, and stated that "we must modernize the administration of our resource development by bringing together programs which are now often scattered through dozens of different agencies." pp. 13119-21
40. FARM PROGRAM. Sen. Wiley inserted resolutions adopted by the Wisconsin Federation of Women's Clubs on various subjects, including sanitation of milk, meat inspection, and food additives. pp. 13124-6
41. LEGISLATIVE PROGRAM. Sen. Long announced that the following bills will be considered Mon., June 27: S. 3275, extension of veterans' loan program, and H. R. 4601, to limit to national security cases the prohibition on payment of annuities to retired employees. p. 13180
42. ADJOURNED until Mon., June 27. pp. 13181-2

HOUSE - JUNE 25

43. ACREAGE ALLOTMENTS. Passed without amendment S. 3117, to treat all basic agricultural commodities alike with respect to the cost of remeasuring acreage allotments (p. 13281). This bill will now be sent to the President. A similar House bill, H. R. 12420, was laid on the table.
44. COLOR ADDITIVES. Passed with amendments H. R. 7624, to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use

of suitable color additives in or on food, drugs, and cosmetics in accordance with regulations prescribing the conditions under which such additives may be safely used (pp. 13298-322). This action was subsequently vacated by the passage of S. 2197, the Senate bill, amended to contain the language of the House bill as amended, and the House bill was laid on the table (pp. 13322-8). The amendments made on the floor were technical amendments. p. 13302

5. WHEAT. Rep. Dixon criticized members of the House Agriculture Committee as being responsible for failure of the House to pass wheat legislation, stating that the Senate wheat bill was a superior bill and should have been acted on rather than the Poage bill. pp. 13343-4
46. WOOL. Agreed to the conference report on H. R. 9322, to make permanent the existing suspension of duties on certain coarse wool (p. 13271). This bill will now be sent to the President.
47. CASEIN. Agreed to the conference report on H. R. 9862, to extend until June 30, 1963, the temporary suspension of duties on imported casein (p. 13272). This bill will now be sent to the President.
48. VETERANS' BENEFIT. The Rules Committee reported a closed rule for consideration of H. R. 7903, to extend the veterans' guaranteed and direct loan programs for 2 years. p. 13347
49. PERSONNEL. Agreed to the conference report on H. R. 9881, to extend until July 1, 1962, the temporary suspension of duty on personal and household effects brought into the U. S. under Government orders (p. 13271-2). This bill will now be sent to the President.

Passed as reported S. 2857, to amend the Civil Service Retirement Act so as to provide for refunds of contributions in the case of annuitants whose length of service exceeds the amount necessary to provide the maximum annuity allowable under such Act. pp. 13270-1

The Rules Committee reported an open rule for the consideration of H. R. 12383, to amend the Federal Employees' Compensation Act to make benefits more realistic in terms of present wage rates. p. 13347
50. MINERALS. Disagreed to the Senate amendments to H. R. 10455, to amend the Mineral Leasing Act of Feb. 25, 1920, and conferees were appointed (p. 13281). Senate conferees have been appointed.

Began debate on H. R. 8860, to stabilize the mining of lead and zinc by small domestic producers on public, Indian, and other lands (pp. 13282-98). On an objection by Rep. Kyl, the final vote on passage was deferred until Mon., June 27.
51. INDEPENDENT OFFICES APPROPRIATION BILL, 1961. Disagreed to Senate amendments to this bill, H. R. 11776, and conferees were appointed (p. 13281). Senate conferees have been appointed.
52. PUBLIC DEBT. Received the conference report on H. R. 12381, to extend for 1 year the public debt limit and the existing corporate normal-tax rate and certain excise-tax rates (H. Rept. 2005). pp. 13344-6
53. FOREIGN AFFAIRS. The Rules Committee reported an open rule for consideration of H. R. 11001, to provide for the participation of the U. S. in the International Development Association. p. 13347
54. ADJOURNED until Mon., June 27. p. 13347

ITEMS IN APPENDIX

55. FOOD PRICES. Extension of remarks of Rep. Quie inserting an article, "You Can't Blame Farmers for High Food Prices." p. A5453
56. EXPENDITURES; BUDGET. Extension of remarks of Rep. Taber inserting a letter from the Director of the Budget "showing that the new and unnecessary appropriations pending for back door expenditures would if passed exceed the budget by over \$10 billion." pp. A5467-8
57. FOOD FOR PEACE. Extension of remarks of Sen. Keating inserting an editorial expressing support for Vice President Nixon's food-for-peace proposal. p. A5479
Rep. Curtis, Mo., inserted an article, "Where Mr. Nixon Stands." pp. A5487-8
58. FARM LABOR. Sen. Javits inserted a New York City church resolution favoring the enactment of legislation relating to aid to migrant workers and their children. p. A5480
Rep. Gubser inserted an editorial, "The Bracero Story -- Growers Tell Their Side." pp. A5490-1
59. ITEM VETO. Rep. Schwengel inserted two editorials favoring item veto authority for the President. p. A5491
60. FARM PROGRAM. Extension of remarks of Rep. Ullman inserting an article, "Agricultural Abundance An Asset," and stating that it "highlights an aspect of our farm program that is rendering a real service to America and the world." pp. A5456-7
Extension of remarks of Rep. Levering stating that "I believe it is most regrettable that the House failed to approve farm legislation ..." and that "with all the imperfections which it contained, the legislation voted down was at least a step in the right direction ..." pp. A5457-8
Extension of remarks of Rep. Berry discussing the failure of passage of the wheat bill and stating that "American agriculture is sick, not because of American agricultural overproduction, but because of oversupply, and that oversupply has resulted and will continue to result from excessive imports." pp. A5458-60
Rep. Bonner inserted the statement of a Future Farmer of America about the modern farmer. p. A5473
Reps. Rees and Dorn inserted a statement of the American National Cattlemen's Association to be submitted to the platform committees of the Republican and Democratic Parties in their July conventions. pp. A5498-9, A5515
Extension of remarks of Rep. Hoeven stating that "the failure of the House of Representatives to accept the Senate wheat bill fixes the responsibility on the shoulders of the Democratic Members of the House," and inserting an article, "Failure on Wheat." pp. A5499-500
Extension of remarks of Rep. Pillion inserting the tabulated results of replies to his questionnaire, including four questions on agricultural problems. p. A5509
61. TERRITORIES AND POSSESSIONS. Extension of remarks of Rep. Saylor urging Congress to begin thinking about advancing those "few small islands ... left in a non-self-governing status ... to full self-government," and insertion of a report making recommendations on how this might be accomplished. pp. A5500-2

H.R. 12417, U.S. Military and Air Force Academies.

Now, for Tuesday, Wednesday, Thursday, Friday, and Saturday the following is the program. Of course, any record votes on Tuesday will go over until Wednesday in view of primaries in Idaho, North Dakota, and South Carolina.

On Wednesday there is a joint meeting to receive the King of Thailand. Calendar Wednesday may be exercised, I want to advise my colleagues. I cannot say definitely. I have not had the opportunity of conferring, and furthermore there are certain imponderables involved in connection with it, or there may be involved, but the bill to be called up, it is my opinion, would be the minimum wage bill.

Then there are the following bills:

H.R. 11001, International Development Association.

H.R. 12465, assessment methods, Federal Deposit Insurance Corporation.

H.R. 12759, the migrant labor bill.

H.R. 4815, transit and sightseeing, District of Columbia. That has been up before but has not been terminated as yet.

H.R. 7903, direct loan agreement, relating to veterans.

S. 19, a wage rate bill relating to the Portsmouth Naval Shipyard.

H.R. 7201, operation of hydroelectric power resources.

H.R. 9996, relating to the importation of surplus property.

H.R. 12383, the Federal employees compensation bill.

H.R. 8665, the Theodore Roosevelt Memorial. Personally, I am very strongly in favor of that.

H.R. 2467, the Chantilly Airport reimbursement bill.

H.R. 12552, the judgeships bill.

The Private Calendar, of course, will be called on Thursday. The bills listed above may not necessarily be called in the order listed.

I make the usual reservation that any further program will be announced later, and that conference reports may be brought up at any time. As far as I know, I have listed every bill with reference to which a rule is outstanding at the present time.

Mr. HALLECK. The conference report on the extension of the excise taxes, of course, has a deadline working against it.

Mr. McCORMACK. Conference reports can be called up without being listed.

Mr. HALLECK. Particularly I have reference to the suggestion that no roll-call votes would be had on Tuesday. I am in complete sympathy with the gentleman's arrangement, that we have consistently followed here when we could, that rollcalls not be had on the day the primaries are held in the various States, but it would seem to me that under these circumstances it might be well to get that conference report up Monday in order to get it passed by the House for action in the other body.

Mr. McCORMACK. I am informed they have until midnight tonight to file a conference report. I shall get in touch with the chairman of the Committee on

Ways and Means and not only convey to him what my friend said but join with my friend in urging that the conference report be brought up Monday. Of course, that can be called up anyway.

Mr. HALLECK. I understand that, but in view of the fact the excise taxes are to be extended, and apparently they are, if they were not extended and the deadline passed it would create considerable difficulty.

Mr. McCORMACK. We will just have to meet that situation. I agree with the gentleman.

Mr. GROSS. Mr. Chairman, will the gentleman yield?

Mr. HALLECK. I yield to the gentleman from Iowa.

Mr. GROSS. Are there any extra copies available of the list of the bills that will be brought up on Monday?

Mr. McCORMACK. I have such a high regard for my friend I will give him my copy.

Mr. HALLECK. If I may reclaim the floor, I may say to the gentleman from Iowa that when these listings are made I will put my copy here on the minority leader's table, and anybody can see it who wants to see it.

Mr. GROSS. We are going to have such a long week end that I wanted to get some opportunity to get these bills that will come up on Monday. After that, it will take care of itself. I wonder if the gentleman will yield further for me to ask the distinguished majority leader if he has any idea as to adjournment.

Mr. McCORMACK. I wish I did. I can answer it two ways, my hope and my objective appraisal.

Mr. GROSS. Does the gentleman still suggest we may recess and come back?

Mr. McCORMACK. Several weeks ago, the gentleman will remember, in response to a question by the gentleman from Iowa [Mr. HOEVEN], I said there was a remote chance of our adjourning sine die. A couple of weeks later, I said there was a very remote chance. Then a couple of weeks later, I said there was a very, very remote chance. Today I would say there is a very, very, very remote chance. Hope is eternal. We are doing everything we can, I assure the gentleman.

Mr. HALLECK. If I may reclaim the floor at this point.

Mr. McCORMACK. Certainly, I would like to get a little lateral support.

Mr. HALLECK. I want to express the hope and, I believe, the conviction, that there is no reason why, if we get down to business and stay down to business, we cannot quit here before the conventions.

Mr. McCORMACK. If we can get the housing bill up, the minimum wage bill, and the school construction bill and get them to conference, I am satisfied that what the gentleman has said can materialize.

Mr. ARENDS. Mr. Chairman, will the gentleman yield?

Mr. HALLECK. I yield to the gentleman from Illinois.

Mr. ARENDS. I would like to know if the majority leader would accept an

amendment to strike out the words "very" in his statement, "very, very, very remote" and just make it "remote."

Mr. McCORMACK. If it would satisfy my friend, we will let the record rest.

I want to be frank here and I am not joking. I gave my friend, the gentleman from Iowa, a serious answer. I said—yes, there is hope. I want to adjourn sine die. Then I said that is my objective opinion, and I was giving the gentleman from Iowa a sincere answer and a frank answer, as I like and try to do when I can whenever I am asked a question. I will do everything I can to try to adjourn sine die and I shall continue to do so. But, frankly, I think there is a remote chance of adjournment sine die. However, we might be able to do it, if we all work together.

Mr. HAYS. Mr. Chairman, will the gentleman yield?

Mr. HALLECK. I yield to the gentleman from Ohio.

Mr. HAYS. If we finish these other two important bills that you talked about today on the calendar, are we going to adjourn over until Monday then?

Mr. McCORMACK. Does the gentleman from Indiana have any further inquiry?

Mr. HALLECK. No, I think that just about does it.

The CHAIRMAN. Without objection, the pro forma amendments are withdrawn.

There was no objection.

The CHAIRMAN. The Clerk will report the next committee amendment.

The Clerk read as follows:

Page 4, strike out all of lines 10 to 19, inclusive, and insert in lieu thereof the following:

"(2) The term 'domestic producer' means any person engaged in producing ores or concentrates from mines located within the United States and its possessions and in selling the material so produced in normal commercial channels.

"(3) The term 'small domestic producer' means a domestic producer who, during the twelve months preceding the first day of the period for which he seeks payments under this Act, has not produced or sold ores or concentrates the recoverable content of which is more than two thousand tons of lead and/or two thousand tons of zinc from each single operating unit producing ores with respect to which he seeks payments under this Act. A domestic producer shall be treated as a small domestic producer with respect to one, but only one, operating unit in any one State or mining district."

Mr. SAYLOR. Mr. Chairman, I move to strike out the last word.

Mr. Chairman, the amendments that are being offered to this bill were very carefully studied by the Committee on Interior and Insular Affairs in the light of prior actions that were taken on similar bills that have come before the House. One of the principal objections which has been made to prior legislation covering a subsidy for the production of minerals grew out of the fact that there was no definition of those people who were qualified to participate under the act. The amendment, which is now being considered, will limit those people who are able to qualify for any subsidy payments.

This is the first time we have had such a provision in any mineral subsidy bill.

Mr. ASPINALL. Mr. Chairman, will the gentleman yield?

Mr. SAYLOR. I yield to the gentleman from Colorado.

Mr. ASPINALL. It was stated heretofore during the discussion on the bill that the gentleman from Pennsylvania, [Mr. SAYLOR], had made a significant contribution to this legislation. It is in the field of this particular statement that one of these amendments that will follow, where we find that contribution. I would like the committee to hear the explanation, because it is a worthwhile provision in the bill.

Mr. SAYLOR. I thank the gentleman for those comments.

Under prior legislation on mineral subsidies, it has been the experience of our Government that many people who had absolutely no experience in the mining field, seeing an opportunity where they could get some money from the Government, went out and began to produce minerals in areas where they had absolutely no hope of ever making a successful production.

The amendment that is now being considered specifically states that a domestic producer must have been in production during the past 7 years, and that he must have been a producer that has not produced more than 2,000 tons of lead or 2,000 tons of zinc. To make sure that this did not turn out to be a windfall bill, but which would be a bill which helped the domestic producers, we went further and specified that a domestic producer could not have more than one operating unit in any one State or in any one mining district. The reason that sentence was added is that experience showed that certain operators under former bills actually went out and opened up four or five or six mines at the same location, doing nothing more than adopting a new name. The purpose of this last sentence is to make sure that that does not apply under the present bill.

Therefore, I sincerely hope that this amendment, together with the other committee amendments which have been prepared, will be adopted.

Mr. EDMONDSON. Mr. Chairman, will the gentleman yield?

Mr. SAYLOR. I yield to the gentleman from Oklahoma.

Mr. EDMONDSON. I would like to express my appreciation, and I feel sure the appreciation of all sponsors of these bills, for the contribution which the gentleman from Pennsylvania [Mr. SAYLOR] has made, in getting a bill which meets the objections and which can be passed and signed into law.

Mr. SAYLOR. I thank the gentleman from Oklahoma.

I would like to make one further statement in regard to an amendment on page 6, and then I will not speak on that amendment. That amendment also is designed to protect the Government against another evil which grew up under the old mining laws, where there were some people, who had already been there and had ore which they could not sell suddenly realized that the Government

was in the business of purchasing minerals. They came along and sold the minerals which had been produced prior to the enactment of the law and the Government paid them for it.

The CHAIRMAN. The time of the gentleman from Pennsylvania has expired.

(By unanimous consent, Mr. SAYLOR was granted 1 additional minute.)

Mr. SAYLOR. The amendment to section 9, on page 6 of the bill, specifically provides that no payments may be made to any producer who qualifies under this bill except for ore which is mined and produced after the act is passed. Those two amendments I feel certain will eliminate all of the evils which arose under prior acts.

The CHAIRMAN. The time of the gentleman from Pennsylvania has again expired.

The question is on the committee amendment.

The committee amendment was agreed to.

The CHAIRMAN. The Clerk will report the next committee amendment.

The Clerk read as follows:

Page 5, line 9, strike "(3)" and insert "(4)".

Mr. ASPINALL. Mr. Chairman, I ask unanimous consent that the remainder of the committee amendments be considered en bloc, be considered as read, and printed in the RECORD.

The CHAIRMAN. Is there objection to the request of the gentleman from Colorado?

There was no objection.

(The other committee amendments are as follows:)

Page 5, line 15, strike out paragraph designation "(4)" and insert in lieu thereof "(5)".

Page 5, line 22, strike out paragraph designation "(5)" and insert in lieu thereof "(6)".

Page 6, line 16, after the word "necessary," insert "but not more than \$4,840,000 per year."

Page 6, line 19, strike out the figure "1964," and insert in lieu thereof "1965, nor shall any payment be made under this Act for ores, or concentrates, therefore, except ores or concentrates produced from a single operating unit which was in production during the whole or some part of the seven years preceding enactment of this Act or produced by a small domestic producer who produced ores or concentrates during the whole or some part of said seven-year period."

Page 7, line 1, strike out "annual reports" and insert "an annual report".

Page 7, line 3, strike out the words "Committees on Interior and Insular Affairs and the Committees on Appropriations of the Senate and the House of Representatives," and insert in lieu thereof "Congress of the United States."

Page 7, line 19, strike out all of section 11 and insert in lieu thereof:

"Sec. 11. (a) Whoever, for the purpose of procuring a payment to which he is not entitled under this Act and the regulations issued pursuant thereto or for the purpose of assisting another to procure a payment to which the other is not entitled under this Act and the regulations issued pursuant thereto, misrepresents any material fact, knowing the same to be false, fictitious or fraudulent, shall be guilty of an offense against the United States and shall be fined not more than \$5,000 or imprisoned not more than two years, or both, and shall thenceforth be entitled to no benefits under this Act."

"(b) Whoever accepts a payment under this Act to which, or any portion of which, he is not entitled, knowing that he is not entitled thereto or whoever, having accepted a payment under this Act to which, or any portion of which, he is not entitled, retains the same knowing that he is not entitled thereto, shall be required, in a civil action instituted by the Attorney General, to refund treble the amount accepted or retained by him. The acceptance or retention of any payment as aforesaid shall also constitute an offense against the United States punishable by a fine or not more than \$5,000 or imprisonment for not more than two years, or both, and any person who shall be convicted of such offense shall thenceforth be entitled to no benefits under this Act."

The CHAIRMAN. The question is on the committee amendments.

The committee amendments were agreed to.

The CHAIRMAN. Under the rule, the Committee rises.

Accordingly, the Committee rose; and the Speaker pro tempore (Mr. ALBERT) having assumed the chair, Mr. DAVIS of Tennessee, Chairman of the Committee of the Whole House on the State of the Union, reported that that Committee, having had under consideration the bill (H.R. 8860) to stabilize the mining of lead and zinc by small domestic producers on public, Indian and other lands, and for other purposes, pursuant to House Resolution 560, he reported the bill back to the House with sundry amendments adopted in the Committee of the Whole.

The SPEAKER pro tempore. Under the rule, the previous question is ordered.

Is a separate vote demanded on any amendment? If not, the Chair will put them en gross.

The amendments were agreed to.

The bill was ordered to be engrossed and read a third time, and was read the third time.

The SPEAKER pro tempore. The question is on the passage of the bill.

The question was taken; and on a division (demanded by Mr. KYL) there were—ayes 64, noes 29.

Mr. KYL. Mr. Speaker, I object to the vote on the ground that a quorum is not present.

The SPEAKER pro tempore. Under the previous agreement further proceedings under the bill will go over until Monday next.

COLOR ADDITIVE AMENDMENTS OF 1960

Mr. DELANEY. Mr. Speaker, by direction of the Committee on Rules I call up House Resolution 559 and ask for its immediate consideration.

The Clerk read the resolution, as follows:

Resolved, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. After general de-

bate, which shall be confined to the bill, and shall continue not to exceed two hours, to be equally divided and controlled by the chairman and ranking minority member of the Committee on Interstate and Foreign Commerce, the bill shall be read for amendment under the five-minute rule. At the conclusion of the consideration of the bill for amendment, the Committee shall rise and report the bill to the House with such amendments as may have been adopted, and the previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit.

Mr. DELANEY. Mr. Speaker, I yield myself such time as I may consume, after which I will yield 30 minutes to the gentleman from Illinois [Mr. ALLEN].

The SPEAKER pro tempore. The gentleman from New York is recognized.

(Mr. DELANEY asked and was given permission to revise and extend his remarks.)

Mr. DELANEY. Mr. Speaker, I yield myself such time as I may consume, and also 30 minutes to the gentleman from Illinois [Mr. ALLEN].

Mr. Speaker, House Resolution 559 provides for the consideration of H.R. 7624, which amends the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics in accordance with regulations prescribing the conditions under which such additives may be safely used. The resolution provides for an open rule with 2 hours of general debate, following which the bill shall be read for amendment under the 5-minute rule.

Mr. Speaker, I had intended to speak on this legislation in the Committee of the Whole, but I shall take this opportunity to make my remarks.

This bill is a continuation of a series of bills to protect the health of the American people and is an outgrowth of an investigation which was made in 1950, 1951, and 1952 by a Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics.

First, we had the Pesticide Act in 1954, to regulate the use of pesticides and insecticides.

Two years ago Congress passed the food additives amendment. This regulated the use of chemicals added to food.

The bill before us today is known as a color additive bill and will regulate the use of colors added to our daily food supply, our drugs and cosmetics.

I anticipate that from time to time there will be other bills to improve the Federal Food, Drug, and Cosmetic Act.

H.R. 7624 originated with the Department of Health, Education, and Welfare, which sent copies of it last year to both the Senate and the House. The Senate committee took the bill, deleted certain portions, and, without holding a single hearing, reported it, and it was passed without any floor debate. I am absolutely opposed to the Senate bill.

In the House, the Interstate and Foreign Commerce Committee gave the bill prolonged study and deliberation, held many public hearings, listened on three occasions to Secretary Flemming, and then unanimously reported the bill. While I do not consider this a perfect

bill, I think it is the best that we can hope for at the present time, and I support it.

The food additives amendment that was enacted 2 years ago shifted the burden of proof of safety for new or insufficiently tested additives from the Government to the sponsors of those additives, and it also contained a clause prohibiting the introduction into food of any cancer-producing substance.

The present bill also shifts the burden of proof from the government to the sponsor of a color dye and it also contains an anticancer provision.

It is vitally important for the protection of the consumer that the producer of a dye be required to test it for safety before permitting its introduction into our foods, drugs, or cosmetics. The Food and Drug Administration simply does not have the facilities or the staff to test all the colors proposed for use. The agency is now engaged in retesting coal-tar dyes it cleared for use many years ago, and as a result of new and more sensitive testing procedures, a number of these dyes have been found to be harmful and have been removed from the approved list. FDA figures that it would take 20 years to complete the retesting program. During that time the public would have to run the risk of daily exposure to dyes which have not been clearly proven to be safe. This cannot be justified on any grounds.

I have referred to the anticancer clause which is contained in the House bill, and which was deleted from the Senate bill. I am convinced that any color additive legislation which does not include this proviso will result in the adulteration of our food by some of the most dangerous chemicals man has developed.

Here is the reason for my concern.

This bill will grant FDA the authority to clear the use of coal-tar dyes at concentrations their scientists find to be safe. However, a number of these dyes have been shown to induce cancer in experimental animals, and are strongly suspected as being able to induce cancer in man. Without the protection of the anticancer provision, it is possible that these dyes could very well find their way into our food supply.

This did happen a few years ago in connection with a pesticide.

Red spider mites are a major crop pest. A chemical concern developed a pesticide which was effective in killing the mites. FDA found that it produced liver damage and malignant tumors in experimental animals, and ruled that no residue of it be permitted to remain on raw agricultural commodities. The sponsoring company then invoked a provision of the 1954 Pesticide amendment and asked that the FDA decision be referred to an advisory committee of scientists for a review and recommendations. This was done, and in spite of the evidence before it, the committee recommended that a residue tolerance of 1 part per million be permitted. FDA reversed its ruling and followed the recommendation.

Although the committee recommended the residue tolerance, it apparently was

not sure of its grounds, since it also recommended that a further 2 year study be made. At the conclusion of this study, the tests showed that the pesticide, known as Aramite, was even more harmful than at first supposed. FDA then took action against the chemical, but the public, meanwhile, had been exposed to it for some 2½ years.

We must not let that happen again. Highly regarded cancer researchers throughout the world hold that repeated exposure to even a minute dose of a cancer-producing agent constitutes a serious health hazard. It is well known that this is the position of the International Union Against Cancer—an organization composed of cancer experts of some 50 countries. After a recent comprehensive study ordered by Secretary Flemming the scientists at the National Cancer Institute supported this position. Other cancer researchers who testified at my request at the food additive hearings in 1957 and still others who appeared at the recent color additive hearings were in accord.

A number of industry representatives have claimed that the anticancer clause has no scientific basis.

On this point, Secretary Flemming in his committee appearance on May 9, 1960, and I quote:

The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound.

This certainly refutes any assertion by industry that the anticancer clause has no scientific backing.

Mr. Speaker, I have placed great emphasis on the anticancer clause because I am convinced that any color additive legislation must have such a provision if the public health is to be adequately protected. I want to clearly and definitely understood that if and when the bill goes to conference I feel that our conferees should stand pat on the House version. The enactment of the Senate bill would be a long step backward.

H.R. 7624 aims at some worthwhile objectives, and it places new responsibility on industry and Government scientists. It may result in the introduction of many synthetic dyes not now in use. If this bill becomes law, it will require constant vigilance on the part of both industry and FDA to insure that no harmful color slip through the net. One mistake in judgment could result in untold human misery.

No legislation of this kind can be perfect, nor should it be considered the final word. Scientific knowledge expands year by year. We must keep our food and drug laws under constant exami-

nation and stand ready to improve them as the need arises.

Mr. Speaker, with this in mind, I urge the adoption of the rule and favorable action on the bill.

Mr. BAILEY. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield to the gentleman from West Virginia.

Mr. BAILEY. I am sure the distinguished member of the Committee on Rules is aware of the fact that the base for most of these additives which this bill would seek to control is coal tar. I should like to ask the gentleman this question. The amendments by the House to the Senate bill: Are they for the purpose of continuing the use of those which the Food and Drug Administration said were harmful or does the bill prohibit their further use?

Mr. DELANEY. The bill does not prohibit; it permits it under certain protective standards.

Mr. BAILEY. Let me ask an additional question at this time. If you deny the use of coal-tar additives, from what source, has the committee ascertained would we get a substitute, or are you going to let the food go unprotected and unpreserved?

Mr. DELANEY. First of all, I personally feel we do not need coal-tar dyes. There are certain restrictions, but they are not barred unless they produce cancer.

Mr. BAILEY. Then the gentleman is answering my question by saying that there is another source from which we could get these preservatives and additives without using coal tar as a base; is that correct?

Mr. DELANEY. I think there are many ways. Vegetable dyes have been used for years, and in my opinion they are safer and should be used. Coal-tar dyes also have been used for many years. A number of them have always been suspected of being cancer producers. However, they are not barred absolutely under this bill unless they are cancer producing.

Mr. BAILEY. I thank the gentleman. Mr. O'BRIEN of New York. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield.

Mr. O'BRIEN of New York. It is my firm conviction that the gentleman from New York has earned and certainly deserves the gratitude of the Congress and of the entire Nation for his unflagging effort to protect the health of the American people.

Mr. DELANEY. I thank the gentleman.

Mr. O'HARA of Illinois. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield.

Mr. O'HARA of Illinois. I join the distinguished gentleman from New York in commending the gentleman from New York [Mr. DELANEY]. I think the entire Nation is indebted to him for the interest and the study he has given to his subject. I have a question. Some weeks ago, possibly 2 or 3 months ago, I was concerned to read in the newspapers of the finding of an eminent scientist that feeding eggs to rats perhaps had produced cancer. I understood there was

some investigation as to the effect feeding certain materials to hens to induce them to lay more eggs might have on human beings who ate those eggs, and what effect they might have in producing cancer.

Mr. DELANEY. I have no observation on that. I merely take the testimony of the experts in an attempt to evaluate and make a proper appraisal. I am not familiar with this particular subject.

Mr. KING of Utah. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield to the gentleman from Utah.

Mr. KING of Utah. I should like to state to the gentleman that in my opinion his name more than that of any other Member of Congress in either body has been associated with the valiant fight against cancer. Before coming to Congress I had heard of the gentleman's distinguished name. I know that his name is a household word in many, many homes in Utah. His name is revered and respected for the great and courageous fight he has waged against cancer and against those cancer-producing ingredients which are unfortunately finding their way all too frequently into our food today. I commend the gentleman on his sponsoring the now well-known Delaney amendment. I congratulate him on his efforts in keeping that amendment in the color additives bill now before the House. I should like to state very clearly that I favor this amendment, and will fight in the years to come if it is my privilege to do so to keep that amendment in our basic food law.

Mr. DELANEY. I thank the gentleman for his statement.

Mr. McCORMACK. Mr. Speaker, will the gentleman yield?

Mr. DELANEY. I yield to the eminent majority leader.

Mr. McCORMACK. I know something about the history of the Delaney amendment, and I thoroughly concur in everything that has been said about my distinguished friend and colleague, the gentleman from New York [Mr. DELANEY]. The people of his district are justified in feeling proud not only of the character of service he renders but particularly in this instance of getting into law what is known as the Delaney amendment, which means so much to protecting the health of all of our American people, men, women, and children. I congratulate my friend. To go further, I congratulate the people of his district for sending him to the halls of Congress so he could carry on the great work he has done in all fields, and particularly in this field.

Mr. DELANEY. I thank the gentleman. I am indebted to the distinguished majority leader for his aid and assistance at all times.

Mr. ALLEN. Mr. Speaker, my good friend, JIM DELANEY, is undoubtedly the most capable man in the House in this House in this field. He certainly knows more about this subject than any other Member. I join in the words of our distinguished majority leader, the nice things he has said about JIM DELANEY's work in this field.

I think, Mr. Speaker, anyone would be naive if they were to get up and attack this bill, which has to do with doing away with the abuses in the field of food, drugs, and cosmetics. At the outset, I assure you I am not opposing this bill. I have had the opportunity to study the hearings and also have read the letters sent up here by the Department of Agriculture signed by E. L. Peterson, Assistant Secretary of Agriculture and also the Acting Secretary of Agriculture with regard to this matter.

If I may be so bold as to make some suggestions, after following the learned man on this subject, the gentleman from New York [Mr. DELANEY], I am convinced that the Senate bill, as passed, is a better bill. I am not saying it on my own authority, but I am saying it on the authority of many chemists within and without the Government.

Mr. Speaker, House Resolution 559 makes in order the consideration of H.R. 7624, a bill designed to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on food, drugs, and cosmetics.

Extensive hearings were held by the Committee on Interstate and Foreign Commerce and I have carefully read the letters written to Hon. OREN HARRIS, chairman of the Committee on Interstate and Foreign Commerce by George P. Larrick, Commissioner of Foods and Drugs; E. L. Peterson, Assistant Secretary of Agriculture; True D. Morse, Acting Secretary of Agriculture; Phillip S. Hughes, Assistant Director for Legislative Reference of the Executive Office of the President; Lawrence E. Walsh, Deputy Attorney General, and Earl W. Kintner, Chairman of the Federal Trade Commission, all contained in the report.

While I am in sympathy with the purposes of this bill, I, after most careful consideration, favor S. 2197 as passed by the other body.

In my opinion the anticancer clause in H.R. 7624, is unnecessary and restrictive.

I also believe that the decision on safety be determined by the Secretary of Health, Education, and Welfare rather than be determined by law. Otherwise, I am certain that our court calendars presently loaded with pending cases in other fields will be even more crowded. After all why should not the Health, Education, and Welfare Department with firsthand scientific information decide as to safety.

It is my sincere hope that when in conference that these two defective provisions be changed. Better still, the bill presently before us should be amended accordingly.

Mr. DELANEY. Mr. Speaker, will the gentleman yield?

Mr. ALLEN. I yield to the gentleman from New York.

Mr. DELANEY. May I say that Secretary Flemming appeared on three occasions before the House Committee on Interstate and Foreign Commerce and before his appearance he had surveys made right up to the minute. He felt that under no circumstances should we delete the cancer amendment. I think,

if you will read the record here of the testimony of witnesses and the deliberations of those who sat over a period of many, many weeks on these hearings, it will clear that matter up. We had a panel of experts. The panel of experts could not agree. They would agree on one point and disagree on another. It is a subject that is not complete and you cannot say here that two and two make four. It is a subject that is open to a great deal of opinion and differences of opinion.

Mr. ALLEN. I agree with the gentleman on that. Of course, as to the anticancer part of the bill, I did discuss it with my good friend, Mr. DELANEY, but in my opinion, and this is also the opinion of many scientists, I repeat, within and without the Government, the anticancer clause in this bill is unnecessary and restrictive. I just bring that to the attention of the House.

There are many chemists within and without the Government whose judgment is that the decision on safety should be determined by the Secretary of Health, Education, and Welfare rather than be determined by law.

Mr. DELANEY. Under the provision of this bill, that is the case.

Mr. ALLEN. No, that is not my understanding.

Mr. DELANEY. We are talking of the color provisions now and, as I read the bill here it is within his discretion.

Mr. ALLEN. That is not my understanding and I have a letter from some very reliable people that I have very recently received.

Mr. DELANEY. If the gentleman is talking of the food additives provision, the Secretary can determine that.

Mr. ALLEN. So I say, Mr. Speaker, that with these two things, particularly the latter part, if the Secretary of Health, Education, and Welfare does not make the decision and if it must be decided according to the law, then you are going to have more legislation in the Federal courts than you have now, and we all know that the courts are pretty crowded now.

So I say I think this committee should consider these provisions which, according to good authorities, are not perfect with the view, perhaps, of amending them and, further, it may be well to consider that when you go to conference to iron out these differences.

Mr. DELANEY. Mr. Speaker, I have no further requests for time and I move the previous question.

The previous question was ordered.

The SPEAKER pro tempore. The question is on the resolution.

The resolution was agreed to.

The SPEAKER pro tempore. The gentleman from Arkansas [Mr. HARRIS] is recognized.

Mr. HARRIS. Mr. Speaker, permit me to make a statement at this time, to advise the Members of the House that it is my intention to ask unanimous consent that this bill be considered in the House as in Committee of the Whole, for the purpose of expediting matters. I think everyone knows that many Members who are here are very anxious to get away to attend a very important

wedding that is to take place this afternoon.

Mr. McCORMACK. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield.

Mr. McCORMACK. May I say that if this bill is disposed of, and we can dispose of the rule on the Gorgas bill, that will be the extent of the legislative program today.

Mr. SCHENCK. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Ohio.

Mr. SCHENCK. I would like to say to the gentleman there is no objection on this side to considering the bill in the House as in Committee of the Whole.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that the bill (H.R. 7624) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions—including maximum tolerances—under which such additives may be safely used, be considered in the House as in Committee of the Whole.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The SPEAKER pro tempore. The Clerk will report the bill.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that the bill be considered as read and open for amendment.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The SPEAKER pro tempore. The Clerk will report the committee amendments.

The Clerk read as follows:

On page 1, line 4, strike out "1959" and insert in lieu thereof "1960".

On page 3, line 9, strike out the quotation mark, and immediately below line 9, insert the following:

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

On page 9, strike out lines 8 through 21 and insert in lieu thereof the following:

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

On page 10, line 19, strike out "and".

On page 10, line 25, strike out the period and insert in lieu thereof "; and".

On page 11, immediately above line 8, insert the following:

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive."

On page 11, lines 10, 12, and 19, immediately after "found" insert "by the Secretary".

On page 11, immediately below line 20, insert the following:

"(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

"(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to an advisory committee; the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him

under clause (11) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee."

On page 17, line 5, immediately after "health" insert the following: "Provided, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection."

On page 17, line 13, immediately after "shall" insert the following: ", subject to the provisions of subparagraph (C) of subsection (b) (5) of this section."

On page 17, lines 16 and 17, strike out "subsection (b), (c), or (e)" and insert in lieu thereof "subsection (b) or (c)".

On page 17, immediately below line 20, insert the following:

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petitioner shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;"

On page 19, line 1, strike out "(1)" and insert in lieu thereof "(3)".

On page 19, line 5, strike out "(2)" and insert in lieu thereof "(4)".

On page 25, line 14, strike out "Regulations" and insert in lieu thereof:

"Except as provided in subparagraph (C) of this paragraph, regulations

On page 25, line 23, immediately after the period insert the following: "Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended."

"(B) If the Secretary by regulation—

"(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1) (E) of this subsection; or

"(ii) has, pursuant to paragraph (1) (C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

"(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review."

On page 28, line 6, strike out "(B)" and insert in lieu thereof "(D)".

On page 28, line 20, strike out "paragraph (1) (A) and (C)" and insert in lieu thereof "paragraph (1) (A) and (C) of this subsection".

On page 29, line 15, immediately after "product" insert the following: ", poultry or poultry product,".

The committee amendments were agreed to.

Mr. HARRIS. Mr. Speaker, I offer a committee amendment.

The Clerk read as follows:

Committee amendment offered by Mr. HARRIS: Page 4, line 11, strike out "(1)" and insert in lieu thereof "(m)".

The amendment was agreed to.

Mr. HARRIS. Mr. Speaker, I offer a committee amendment.

The Clerk read as follows:

Committee amendment offered by Mr. HARRIS: Page 19, line 6, strike out "third" and insert "fourth".

The amendment was agreed to.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent that the bill be printed in the RECORD showing the amendments.

The SPEAKER. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

(The bill, as amended, reads as follows:)

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this act may be cited as the "Color Additive Amendments of 1960."

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Definitions

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or"

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive."

(2) Section 402(c), as amended, of such act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(3) Section 403 of such act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

(b) (1) Clause (4) of section 501(a) of such act (relating to drugs deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows: "(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

(c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

Regulations to assure safety of color additives for foods, drugs, and cosmetics

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "Sec. 406." in such section;

(2) repealing section 504;

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or (b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604."; and (C) inserting the word "or" after "501 (b)."

(b) Section 706 of such Act is amended to read as follows:

"Listing and certification of color additives for foods, drugs, and cosmetics"

"When Color Additives Deemed Unsafe"

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a) (4), or section 601(e), as the case may be, unless—

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

"Listing of Colors"

"(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or

articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however*, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5) (A) In determining for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive,

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

"(B) A color additive (1) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

"(C) (1) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e)) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for

a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

"(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b) (5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except

that the Secretary may (prior to such ninety-day day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006 (c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

"(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409 (f) (2); and

"(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

"Fees

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions

"(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

Confidentiality of trade secrets

SEC. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

Changes in cross-references and terminology

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(i) thereof relating to forgery or unauthorized use of certain identification devices, "404, 406(b), 504, 506, 507, or 604", and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Definitions

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same

meaning as they have, or had when in effect, under the basic Act.

Effective date

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

Provisional listings of commercially established colors

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of

the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1)(E) of this subsection; or

(ii) has, pursuant to paragraph (1)(C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(D) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemption from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1) (A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the

protection of the public health to increase or dispense with such temporary tolerance limitation.

Effect on Meat Inspection and Poultry Products Inspection Acts

Sec. 204. Nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).

Mr. GROSS. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. Mr. Speaker, I move to strike out the last word.

Mr. Speaker, I may say to the gentleman from Iowa that I intend to explain the bill, but I will be glad to yield to him at this time if he wishes.

Mr. GROSS. I thank the gentleman.

I wish to inquire if there is any substantial added cost to the Treasury contemplated under this bill?

Mr. HARRIS. No; not at all.

COLOR ADDITIVES AMENDMENTS (H.R. 7624)

Mr. Speaker, the committee bill, H.R. 7624, was reported unanimously by the Committee on Interstate and Foreign Commerce. It is designed to meet a pressing need for replacing the inconsistent, and in part outmoded, provisions which now govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a specifically sound and uniform system for the listing of color additives of any kind which may safely be used in foods, drugs or cosmetics, subject, when necessary, to appropriate tolerance limitations and other conditions of use and to official certification of batches of color so as to assure the safety of such use to the consumer.

GENERAL SUMMARY

In brief, the committee bill, first, takes color additives out of the scope of the food additives amendment of 1958; second, repeals the present provisions of the Federal Food, Drug, and Cosmetic Act for the listing and certification of "harmless" coal-tar colors (secs. 406(b), 504, and 604); third, enacts new, integrated provisions for the separate listing of suitable color additives, safe for use in food, drugs or cosmetics, under such conditions—including tolerance limitations—as the Secretary of Health, Education, and Welfare may find necessary to assure the safety of the uses permitted; fourth, provides for the certification (or exemption from certification) of listed color additives for such permitted uses; fifth, adapts the adulteration and other provisions of the Federal Food, Drug, and Cosmetic Act to the substantive and other changes involved in the above-mentioned changes; and sixth, contains transitional provisions for commercially established colors.

BACKGROUND INFORMATION

Under the Federal Food, Drug, and Cosmetic Act the treatment of color additives differs radically as between so-called coal-tar colors and other colors.

1. COAL-TAR COLORS

The term "coal-tar color" has been interpreted to apply not only to substances which are coal-tar derivatives but also to synthetic substances so related in their chemical structure to a coal-tar constituent as to be capable of derivation therefrom even when not actually so derived.

So-called coal-tar colors are regulated under the act through similar sets of provisions in chapters IV Food, V Drugs, and VI Cosmetics. The act requires the Secretary of Health, Education, and Welfare to provide by regulation for listing and certifying batches of "coal-tar colors which are harmless and suitable for use" in food, drugs, and cosmetics.

Food containing coal-tar color is deemed adulterated under section 402(c) of the act unless the color is from a batch certified by the Secretary under section 406. Section 406(b) then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in food and to provide for certifying batches of such colors.

A drug containing a coal-tar color solely for coloring purposes is deemed adulterated by section 501(a)(4) unless the color is from a batch certified by the Secretary under section 504. Section 504 then directs the Secretary to provide for listing coal-tar colors that are harmless and suitable for use in drugs for purposes of coloring only, and for certifying batches of such colors.

A cosmetic—other than a hair dye, which is defined to exclude eyelash and eyebrow dyes—containing a coal-tar color is deemed adulterated by section 601(e) unless the color is from a batch certified by the Secretary under section 604. Section 604 then directs the Secretary to provide for listing of coal-tar colors that are harmless and suitable for use in cosmetics, and for certifying batches of such colors.

The Secretary of Health, Education, and Welfare is without authority to admit a coal-tar color to listing under tolerance limitations; it must be harmless per se in order for the Secretary to admit it to listing—*Flemming v. Florida Citrus Exchange* (358 U.S. 153 (1958)).

One exception to the prohibition against the listing of a coal-tar color under tolerance limitations was made by the Congress in Public Law 86-2 to permit the temporary listing and certification of the color citrus red No. 2 for the coloring of mature oranges under tolerances found to be safe by the Secretary of Health, Education, and Welfare.

2. OTHER COLORS

A coloring material not classified as a coal-tar color is not subject to any pretesting, listing, or certification requirements in the case of cosmetics or drugs except as pretesting may be required for a coloring component as an incident to official clearance of a "new drug" under the "new drug" provisions of the act.

Non-coal-tar coloring materials used in food, when such materials are not generally recognized by experts as safe, are classified as "food additives" under the Food Additives Amendment of 1958—

Public Law 85-929. Under section 402(a)(2)(C) of the act, a food which is, bears, or contains a "food additive" is deemed to be adulterated if the additive is unsafe within the meaning of section 409. Under section 409 the food additive is deemed unsafe unless it and its use, or intended use, conform to a regulation issued by the Secretary announcing the conditions, including the establishment of tolerance limitations, under which the additive may be safely used. Food colors which were in commercial use before January 1, 1958, are allowed a grace period not later than March 6, 1961, for compliance with the provisions of the Food Additives Amendment of 1958. Such "food additive" colors, however, are not subject to any requirement of "batch" certification.

NEED FOR LEGISLATION

The principal reasons which give rise to the need for this legislation may be summarized as follows:

First. The law with respect to coal-tar colors—and this comprises most synthetic colors—is not in consonance with modern concepts of consumer protection, in that it does not allow the Secretary of Health, Education, and Welfare to list a color for safe use under regulations which place a limit on the amount of a color that may be used on an article and to establish other conditions of use. For food, and for drugs and cosmetics other than those externally applied, the Secretary must ban the use of such a color completely, as not being harmless, if it is found to be toxic in the laboratory when fed to animals in some concentrations, even though its actual level and manner of use may be completely safe. For externally applied drugs and cosmetics, the same principle applies if toxicity appears in the laboratory in some concentrations by any relevant type of test, even though its actual level and manner of use may be wholly safe.

Prior to delisting proceedings by the Department of Health, Education, and Welfare there were 19 colors listed for unrestricted use in food, drugs, and cosmetics, 69 colors listed for unrestricted use in drugs and cosmetics, and 30 colors listed for use only in externally applied drugs and cosmetics, a total of 118 straight colors listed for certification. Seven colors have been removed from the food, drug, and cosmetic list and have been relisted for external use in drugs and cosmetic colors, so that we now have 12 food, drug, and cosmetic colors, 69 unrestricted drug and cosmetic colors, and 37 drug and cosmetic colors for external use. The Department has proposed that other colors be removed from listing and certification.

Only last week the Food and Drug Administration announced a tentative decision removing 14 coal-tar colors used principally in lipsticks from the list of permitted colors for unrestricted use in drugs and cosmetics. This decision was based upon an evaluation of evidence presented at a public hearing granted color, lipstick, and drug manufacturers. A final decision on delisting will be made after consideration of any objections which may be filed by the affected parties to the proposed order.

The principle of allowing colors to be used under tolerance limitations was endorsed, in 1956, by a committee of recognized scientists appointed by the National Academy of Sciences to review the coal-tar color research program of the Food and Drug Administration, as indicated by the following excerpt from the committee's report:

This committee feels compelled to indicate that certification of a compound as harmless and suitable for use in food, drugs, and cosmetics as required under present law is unrealistic unless the level of use is specified (report of the National Academy of Sciences-National Research Council Ad Hoc Advisory Committee To Review the Food and Drug Administration's Research Program on Coal-tar Dyes, June 1956).

Second. The theoretically perfect public health protection once thought to be accorded by the present law regarding coal-tar colors has turned out to be in fact inadequate. While theoretically, only harmless colors may be listed, a retesting program of the Food and Drug Administration, employing the most modern testing techniques, has led to the discovery that many of the so-called coal-tar colors on the list may in fact be toxic in some concentrations. Yet, the Secretary of Health, Education, and Welfare cannot take a particular color off the list until he establishes its toxicity by laboratory tests, a process which for the list as a whole may take as much as 20 years. Under the bill, there would, in general, be a maximum of 2½ years during which the retesting process for the established colors would have to be completed—primarily by industry—and during which the Secretary could establish temporary tolerance limitations, at zero level if necessary, to protect the public health. This maximum period could be extended only where, in a particular case, such extension is necessary to complete the required safety tests for a color and is found consistent with protection of the public health.

Third. There is a need for making applicable to all color uses and all types of color—whether they be coal-tar colors or others—the same pretesting requirements and, where necessary for the protection of color users and consumers, the same requirement for certification of colors to assure their purity and identity with those listed as safe. At present there are no provisions for the certification of noncoal-tar colors. There is, moreover, no pretesting requirement for non-coal-tar additives as such, other than food additives.

Fourth. Unless the law, as proposed by the bill, is brought into conformity with modern methods of control by incorporation of the safe-for-use principle, it will become increasingly difficult, and may eventually become impossible, to find permissible colors to supply the demand for various important color uses on the part of consumers as well as the food, drug, and cosmetic industries. From the standpoint of the public interest there is no compensating advantage for the inflexibility of the present law in this respect.

The food, drug, cosmetic, and color industries find themselves in a serious situation as the result of the removal of color after color from the lists under

the present inflexible provisions of the law. Unless the law, by permitting the listing of colors under safe tolerances, is brought into line with present-day methods of control, the emergency will grow and deepen, an emergency which the Secretary of Health, Education, and Welfare believes could be relieved for most established colors on a sound and permanent basis by enacting the provisions of this bill without in any conflicting with the need for adequate protection of the public health.

There is no justification, from the point of view of the public interest, in driving either color manufacturers or food, drug, or cosmetic producers, dependent upon the use of color, out of business where the particular use of color involved is one which can safely be admitted under proper conditions of use—including tolerance limitations and certification requirements—established by the Department of Health, Education, and Welfare.

The scientifically sound principle that we must consider conditions of use when passing on suitability and safety of a color additive has recently been approved by Congress in temporary emergency legislation—Public Law 86-2—with respect to one coal-tar color, i.e., citrus red No. 2 for use in coloring mature oranges, after previous adoption of the "Safe-for-use" principle in the Food Additives Amendment of 1958—Public Law 85-929. In reporting upon the emergency legislation for citrus red No. 2, this committee said:

It is specifically provided that the provisions of this bill will become inoperative on August 31, 1961, or before that time if general legislation affecting coloring materials for food is enacted by the Congress. The reason for the time limit is that this emergency legislation, which will meet the immediate needs of the citrus industry without permanently engrafting on the basic Food, Drug, and Cosmetic Act a new principle of tolerances for coal-tar colors which is not applicable to foods generally. The expiration date has been so fixed as to allow the Congress ample time to consider the application of this principle to all foods.

It is the intention of the committee as soon as feasible to study amendments to the Federal Food, Drug, and Cosmetic Act dealing with color additives generally, since the need for such legislation has been amply demonstrated to this committee (86th Cong., 1st sess., H. Rept. 88).

The bill—by permitting, for a reasonable period, the provisional listing and certification of heretofore commercially established colors, under temporary tolerances where necessary for public-health protection, pending the development of the scientific data required for a definitive determination as to the listing of these colors under the permanent provisions of the bill—would permit an orderly transition to the control procedures of the bill. At the same time, the bill would establish on a permanent basis a sound system of color regulation fully protective of consumer interests.

EXPLANATION OF COMMITTEE BILL

The bill would change existing law in the following major respects:

First. Uniform criteria of admissibility. It would do away with the differ-

ences in legal requirements and treatment as between the so-called coal-tar colors and other color additives, and would establish an integrated and internally consistent basis for determining the admissibility of any coloring material for use in or on foods, drugs, or cosmetics—other than hair dyes. This would be accomplished by excepting color additives—as defined in the bill—from the term "food additive"; repealing the present provisions for listing and certification of coal-tar colors; enacting, as part of a single section—section 706—comprehensive provisions for the separate listing of any color additives suitable and safe for general or restricted use in foods, drugs, or cosmetics, and for their certification—or exemption from certification—and making other amendments to the act to mesh with these provisions.

The bill would embrace all color additives whether or not synthesized and whether or not capable of derivation from a coal-tar constituent. From the point of view of determining safety of use, there is no sound scientific basis for distinguishing between a color additive extracted from a plant, animal, or mineral source and one which is synthesized with a chemical structure which will bring it under the term "coal-tar color." The bill would therefore establish common ground rules for all such colors.

Doing away with the distinction between so-called coal-tar colors and other coloring substances will have the incidental effect of establishing a pretesting and safety clearance requirement for the latter type of colors in the case of drugs or cosmetics. The lack of consumer protection inherent in the absence of such a requirement was forcefully brought to the attention of Congress by the investigations and recommendations of the House Select Committee To Investigate the Use of Chemicals in Foods and Cosmetics, the Delaney committee in the 82d Congress, and by the hearings culminating in the enactment of the Food Additives Amendment of 1958.

Second. Safety-of-use principle. The bill adopts for all colors, and for all color uses covered by it, the basic principle of the Food Additives Amendment of 1958, by providing for the official listing of color additives for any use in or on foods, drugs, or cosmetics, for which they are determined to be safe, subject to such conditions of use (including maximum tolerance limitations) as are determined to be necessary to assure the safety of such use.

Third. Delaney anticancer clause. One provision of the bill which aroused considerable controversy in the hearings on this legislation is proposed section 706(b)(5)(B) appearing on page 11, line 8, of the reported bill, and often referred to as the Delaney anticancer clause.

This clause provides that a color additive shall be deemed unsafe and shall not be listed for any use which will or may result in ingestion of all or any part of such additive if the additive is found to induce cancer when ingested by man or animal, or if it is found to induce cancer in man or animal by other tests, not involving ingestion, which are considered to be appropriate for the evalua-

tion of the safety of additives for use in food.

This clause also provides that a color additive shall be deemed unsafe and shall not be listed for any use which will not result in ingestion of any part of such additive if, after tests which are appropriate for the evaluation of the safety of the additive for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

A similar anticancer clause is included in the Food Additives Amendment of 1958 to the Federal Food, Drug, and Cosmetic Act—Public Law 85-929.

There are many unknowns about cancer that are yet to be solved. We do know, however, that today cancer is second only to heart disease as a cause of death among the American people. Every year, approximately 250,000 people die of cancer in this country. Approximately 450,000 new cases of cancer are discovered each year. At any given time about 700,000 persons are under treatment for cancer.

Expert testimony before the committee showed that scientific inquiry into the incidence of cancer among certain occupational groups has been traced, in several instances, to specific substances involved in their environment. Laboratory experiments have shown that a number of substances when added to the diet of test animals have produced cancers of various kinds in the test animals. It is this fact—namely, that small quantities of certain materials over a period of time will cause abnormal cell growth in animals—that gave rise to the Delaney anticancer clause in the Food Additives Amendment.

The Secretary of Health, Education, and Welfare very strongly urged the retention of the Delaney clause in the reported bill. The reason for his position may be summarized from his statement to the committee as follows:

The preponderance of scientific evidence clearly dictates our position: Our advocacy of the anticancer proviso in the proposed color additives amendment is based on the simple fact that no one knows how to set a safe tolerance for substances in human foods when those substances are known to cause cancer when added to the diet of animals. I should like to underline again one statement in particular which I read earlier from the summary of Dr. [G. Burroughs] Mider's review of the role of certain chemical and physical agents in relation to cancer. It is this:

"No one at this time can tell how much or how little of a carcinogen would be required to produce cancer in any human being, or how long it would take the cancer to develop."

This is why we have no hesitancy in advocating the inclusion of the anticancer clause.

Unless and until there is a sound scientific basis for the establishment of tolerances for carcinogens, I believe the Government has a duty to make clear—in law as well as in administrative policy—that it will do everything possible to put persons in a position where they will not unnecessarily be adding residues of carcinogens to their diet.

The population is inadvertently exposed to certain carcinogens. Ultraviolet light occurs in sunlight. The burning of most

fuels produces some minute quantities of chemical compounds that elicit cancer in experimental animals, and some of the same agents can be identified in soot, tars, dusts, and similar residues—even from the atmosphere. In view of these facts, it becomes all the more imperative to protect the public from deliberate introduction of additional carcinogenic materials into the human environment.

Whenever a sound scientific basis is developed for the establishment of tolerances for carcinogens, we will request the Congress to give us that authority. We believe, however, that the issue is so important that the elected representatives of the people should have the opportunity of examining the evidence and determining whether or not the authority should be granted.

Many have oftentimes expressed the fond hope that the day is not far distant when we shall be able to control cancer. A dramatic breakthrough in this sense may never come. Rather, the progress—looked at from the standpoint of reducing the number of cases of cancer—may come only as we are willing to give heed to the kind of leads that are incorporated in the document prepared by Dr. Mider. It is clear that if we include in our diet substances that induce cancer when included in the diet of test animals, we are taking a risk. In the light of the rising number of cases of cancer, why should we take that risk? Why shouldn't the Government do everything possible to see to it that we do not involuntarily take that risk?

This, I believe, is as far as our discretion should go in the light of present scientific knowledge. We have no basis for asking Congress to give us discretion to establish a safe tolerance for a substance which definitely has been shown to produce cancer when added to the diet of test animals. We simply have no basis on which such discretion could be exercised because no one can tell us with any assurance at all how to establish a safe dose of any cancer-producing substance.

Unless and until cancer research makes a breakthrough at this point, the principle in the anticancer clause is sound. (Statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare, before the House Committee on Interstate and Foreign Commerce, January 26, 1960.)

The Secretary further stated that, even if the Delaney clause is deleted from the bill, he believes that he has the authority to apply the policy that is reflected in that clause but he urged the Congress to join with the executive branch in giving added assurance to the public by including the anticancer clause in the proposed color additives legislation.

The committee heard a large number of witnesses on the anticancer clause, including a distinguished panel of scientific experts on cancer selected by Dr. Detlev W. Bronk, president of the National Academy of Sciences.

One industry witness objected to any anticancer clause. Another witness argued that it is possible to establish safe tolerance levels for substances that produce cancer when fed to test animals. Some would have the ban on cancer producers apply only to colors that induce cancer when ingested in an amount and under conditions reasonably related to their intended use. And another witness proposed that the cancer clause be taken out of its present position in the bill and added with material language changes to section 705(b)(5)(A) so that it would

become simply one of the factors for the Secretary to consider in evaluating the safety of a color additive.

It is evident that such proposed changes are intended to give the Secretary the right to establish tolerances for presumed safe levels of colors that produce cancer when tested under appropriate laboratory conditions. Thus, any of the proposals, if adopted, would weaken the present anticancer clause in the reported bill. For this reason all of the proposed changes were rejected by the committee.

The panel discussed in considerable detail the scientific problems that confront us in connection with determination of the cancer-producing potentials of chemicals. They pointed out the difficulties of designing and conducting an experiment to determine whether a substance is a cancer producer for man and the difficulties in evaluating the test data after they are obtained.

Some of the panel members have suggested that despite these difficulties, in extraordinary cases, the Secretary of Health, Education, and Welfare should have the authority to decide that a minute amount of a cancer-producing chemical may be added to man's food after a group of scientists consider all the facts and conclude that the quantity to be tolerated is probably without hazard.

In commenting on this testimony, the Secretary of Health, Education, and Welfare said:

The Department's position is that the proposed color additives legislation should include an anticancer clause that makes illegal the use of any color that will induce cancer when tested by appropriate methods. We believe this position to be the only sound public policy in view of the fact that our experts tell us present scientific techniques do not permit them to state unequivocally how much or how little of a substance that induces cancer when administered to animals will induce cancer when administered to man.

The rallying point against the anticancer provision is the catch phrase that it takes away the scientists' right to exercise judgment. The issue thus made is a false one, because the clause allows the exercise of all the judgment that can safely be exercised on the basis of our present knowledge. The clause is grounded on the scientific fact of life that no one, at this time, can tell us how to establish for a man a safe tolerance for a cancer-producing agent. Until cancer research makes a breakthrough at this point, there simply is no scientific basis on which judgment or discretion could be exercised in tolerating a small amount of a known carcinogenic color or food additive. As I pointed out in my original testimony, the opposition to inclusion of an anticancer clause arises largely out of a misunderstanding of how this provision works. It allows the Department and its scientific people full discretion and judgment in deciding whether a substance has been shown to produce cancer when added to the diet of test animals. But once this decision is made, the limits of judgment have been reached and there is no reliable basis on which discretion could be exercised in determining a safe threshold dose for the established carcinogen.

So long as the outstanding experts in the National Cancer Institute and the Food and Drug Administration tell us that they do

not know how to establish with any assurance at all a safe dose in man's food for a cancer-producing substance, the principle in the anticancer clause is sound (statement by Hon. Arthur S. Flemming, Secretary of Health, Education, and Welfare before the House Committee on Interstate and Foreign Commerce, May 9, 1960).

In view of the uncertainty surrounding the determination of safe tolerances for carcinogens, the committee decided that the Delaney anticancer provision in the reported bill should be retained without change.

The committee adopted an amendment, discussed below, which provides for an ad hoc advisory committee to study and report on the question of whether a color additive is a carcinogen.

Fourth, Comprehensive lists. The bill retains the approach of the present coal-tar color provisions in providing for comprehensive lists of colors, instead of attempting to carve out an exception from listing for colors "generally recognized" by experts as safe for use. While there may have been justification in the case of the Food Additives Amendments of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—the Secretary of Health, Education, and Welfare does not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color. It may be noted, however, that a committee amendment to the bill deems a color additive to be suitable and safe for the purpose of listing for use generally in food, where there is in effect a published finding of the Department that the substance is generally recognized as safe for its intended use within the meaning of the provisions exempting such substances from the Food Additives Amendments of 1958.

Fifth, Certification and exemptions from certification. While providing for certification of batches of listed colors, as existing law does for coal-tar colors, the bill would permit the Secretary to grant exemptions from the requirement of certification where certification is not necessary to protect the public health. The present requirement of certification for coal-tar colors is intended to assure food processors and housewives that the color is free from toxic impurities and otherwise complies with regulations defining the color's identity. The committee agrees with the Secretary of Health, Education, and Welfare, however, that authority to exempt colors from the certification requirement is desirable, especially since the coverage of the law is broadened to include all types of substances capable of imparting color.

Sixth, Effective date and transitional provisions. The amendments made by the bill to the Federal Food, Drug, and Cosmetic Act—that is, title I of the bill—

would become effective as soon as the bill is enacted.

However, in order to allow on an interim basis, for a reasonable period, the use of commercially established color additives to the extent consistent with the public health, pending completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the new permanent provisions of the bill, the bill provides for the provisional listing of such color additives, and their certification—or exemption from certification in certain cases. The "commercially established" color additives falling under these transitional provisions are first, those coal-tar colors of which a batch or batches were actually certified prior to the date of enactment of the bill; and second, those non-coal-tar colors, and synthetic beta-carotene, which were commercially used or sold prior to that date for food, drug, or cosmetic use.

Provisional listings would be subject to appropriate temporary tolerance limitations and other conditions of use when deemed necessary for the protection of the public health during the period of provisional listing. The bill would permit establishment of a zero tolerance or removal from the provisional list at any time during this transitional period when the protection of the public health so requires.

A provisional listing would be automatic except that, in the case of a coal-tar color which was "delisted" prior to the enactment date of the bill, the color could be provisionally listed under these transitional provisions only upon request to the Secretary of Health, Education, and Welfare.

In order to enable the Secretary to compile and promulgate a list of colors which are deemed provisionally listed without specific request to the Secretary, and in order to enable him to determine temporary tolerances for such colors, the Secretary would, after reasonable public notice for submission of data, be required, for the time being, to fix temporary tolerances at zero level with respect to those colors and uses thereof for which the data available to him do not establish a reliable basis for inclusion in a list of colors deemed provisionally listed and for determining the prevailing levels of use thereof prior to the enactment date.

In general, a provisional listing would terminate no later than the end of the 2½-year period beginning on the date of enactment. However, where necessary to complete the scientific testing required for a particular additive, the Secretary could extend this period with respect to a particular color additive or use, if this is consistent with the protection of the public health and with the objective of completing these tests as soon as practicable. Of course, a provisional listing of a color additive for any use, if not sooner terminated, would cease upon listing of the additive for such use under the permanent provisions of the bill.

Seventh, Deception. A witness before the committee suggested amending proposed section 706(b) (6) to add the word "harmful" before the word "deception" so as to provide that the Secretary shall

not list a color additive for a proposed use if the data before him show that such proposed use would "promote harmful deception of the consumer in violation of this act or would otherwise result in misbranding or adulteration within the meaning of this act."

The Federal Food, Drug, and Cosmetic Act prohibits, among other things, the introduction of an adulterated or misbranded food, drug, or cosmetic into interstate commerce, or the adulteration or misbranding of any food, drug, device, or cosmetic in interstate commerce, or while held for sale after interstate shipment. Furthermore, the food additives amendment—section 409(c) (3) (B) of the act—specifically prohibits the Secretary from issuing a regulation prescribing the conditions under which a food additive may be safely used if a fair evaluation of the data before him shows that the proposed use of the additive would "promote deception of the consumer in violation of this act or would otherwise result in adulteration or in misbranding of food within the meaning of this act."

The committee is of the opinion that it would be unsound policy to legislate against deception of the consumer in the food additives law and against harmful deception of the consumer in the color additives law. Obviously, the provision against deception of the consumer should be identical under both sections of the law. It should be emphasized that we are dealing here solely with deception which would violate the law. Among the relevant provisions of the Food and Drug Act aimed at deception are those which deem a food to be adulterated:

(3) If damage or inferiority has been concealed in any manner; or

(4) If any substance has been added hereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is. (Sec. 402(b) (3) and (4) of the Federal Food, Drug, and Cosmetic Act.)

Examples of coloring practices that would promote deception of the consumer in violation of the basic act were cited by the Secretary of Health, Education, and Welfare as follows: First, the use of artificial color in egg noodles to hide a deficiency in eggs; second, the use of artificial color in immature apples or oranges to make the fruit appear mature; third, the use of artificial color in tomato catsup, or juice, or canned tomatoes prepared from immature raw materials; and fourth, the use of artificial color in stale red meat to make it appear fresh.

The Secretary of Health, Education, and Welfare, by letter dated April 21, 1960, has advised the committee that use of artificial coloring, under proper labeling declaration, on mature oranges would not promote deception in violation of the Federal Food, Drug, and Cosmetic Act. Likewise, the Food and Drug Administration, by letter dated June 2, 1960, has advised the committee that the use of safe coloring in oleomargarine or margarine, with appropriate label declaration, or in butter would not promote deception in violation of the act.

These letters are included in the appendix to the committee report.

Eighth. Recommended amendments to Food Additives Amendment. The Secretary of Health, Education, and Welfare recommended the adoption of two amendments to the Food Additives Amendment of 1958. These proposed amendments are: First, a modification of the Delaney anticancer clause to provide that additives used in animal feed which do not adversely affect the animal and which leave no residue either in the animal after slaughter, or in any food product obtained from the living animal, be exempt from the provisions of the clause. The Secretary also suggested a corresponding change with respect to color additives; and second, a modification of the "prior sanction or approval"—grandfather clause—section 201(s) (3) of the act.

The Secretary's letter of May 13, 1960, submitting these amendments is included in the appendix to the committee report.

The committee did not consider the above-mentioned amendments because they involved amendments to the food additive amendment which are not directly germane to this bill. They may be considered at a later date.

EXPLANATION OF PRINCIPAL COMMITTEE AMENDMENTS

First. Agricultural chemicals affecting color—page 3, beginning on line 10 of reported bill. The committee was advised that certain pesticide chemicals used in fruit production have the effect not only of protecting the trees against plant diseases but also of supporting or otherwise affecting natural plant processes which thus result in the production of better color and finish in the fruit. Also, some plant growth regulators, when applied to plants, likewise enhance the development of normal color in the produce of such plants. Some fear has been expressed that such chemicals and plant regulators could be considered to fall within the scope of the definition of "color additive" in section 101(c) of the bill since they have the ability to promote the coloring of raw agricultural commodities.

The committee agrees with the Secretary of Health, Education, and Welfare that such chemicals and plant nutrients are not color additives within the meaning of the basic definition of color additive in this bill, since they merely promote the development of the natural color of produce as the result of the normal physiological processes of the plant or produce. To make this clear, however, the committee has inserted an amendment to the effect that the term "color additive" in section 101(c) of the bill shall not be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical which affects the color of fruit or other raw agricultural commodity which is the produce of the soil solely through its effect on plant metabolism or enzymatic processes either before or after harvest. Pesticide chemicals are regulated under section 408 of the Federal Food, Drug, and Cosmetic Act and under the Federal Insecticide, Fungicide, and Rodenticide

Act—61 Stat. 163; 7 U.S.C. 135-135k—and there is no necessity for subjecting them to additional regulation under the color additive amendments when their sole effect on color is through such metabolic or enzymatic processes.

It is not the intention of the committee, however, to exempt from the provisions of this bill any chemical or nutrient if it also contains a dye, pigment, or other substance whose function is to impart color to the fruit or other raw agricultural commodity.

The views of the Secretary of Health, Education, and Welfare in letters to the committee dated February 8, 1960, and April 21, 1960, and the letter of the Assistant Secretary of Agriculture dated April 14, 1960, expressing their views on this subject, in which the committee concurs, are shown in the appendix to the committee report.

Second. Color additives exempted under Food Additives Amendment—page 9, beginning on line 8 of reported bill. This committee amendment revises proposed section 706(b) (4) by transferring the provisions of subparagraphs (B) and (C) thereof, in consolidated and modified form, to proposed section 706(b) (5) (see discussion immediately below) and adding a proviso to the revised section 706(b) (4) providing that a color additive shall be deemed to be suitable and safe for listing for use generally in or on food while there is in effect a published finding by the Secretary declaring that such additive is exempt under the Food Additives Amendment of 1958 because of its being generally recognized by qualified experts as safe for its intended use as provided in section 201(s) of the act.

Third. Analytical methods for color additives—page 11, beginning on line 1 of reported bill. This committee amendment adds a new subparagraph (iv) to proposed section 706(b) (5) (A) in the bill, which consolidates and modifies the provisions of subparagraphs (B) and (C) of proposed section 706(b) (4) in the bill as introduced. These subsections deal with practicable methods of analysis for color additives and for determining the identity and quantity of such additives or their reaction products in foods, drugs, and cosmetics.

The net effect of the change would be to require the Secretary to determine whether, with respect to particular color additives and proposed listings, all of the analytical methods described both in the original bill and in the proposed amendment are needed and, to the extent that they are, to refuse a listing unless these methods exist and are made available to him, whereas, under the bill as originally introduced, the Secretary must refuse a listing unless all of the described methods of analysis are available to him, without regard to whether, with respect to a particular proposed listing of a color additive, such methods are in his judgment actually needed.

The proponents of the amendment believe that some of the requirements of the original bill, and in particular the requirement that there be practicable methods for determining the identity and quantity of any substance formed in or on food because of the use of a color

additive, could not always be met in the present state of knowledge and that, in those cases in which there is no need for such a method of analysis for adequate public health protection, the requirement would unnecessarily bar the use of a color additive which would be perfectly safe. The committee amendment meets this objection without impairing consumer health protection.

Fourth. Ad Hoc Scientific Advisory Committee on Carcinogenicity of Additive—page 11, beginning on line 21 of reported bill. This committee amendment provides that in any proceeding for the issuance, amendment, or repeal of a regulation by the Secretary of Health, Education, and Welfare listing a color additive, any person who will be adversely affected may request that the petition or order thereon or the Secretary's proposal which is the subject of the proceeding be referred to an advisory committee for a report and recommendations with respect to any matter arising under proposed section 706(b) (5) (B) of the bill, commonly referred to as the Delaney anticancer clause, if such matter is involved in such proposal or order and requires the exercise of scientific judgment.

Upon such request, the Secretary shall forthwith appoint an advisory committee and shall refer to it for study and for a report and recommendations the question arising under section 706(b) (5) (B). The Secretary may also refer such a matter to such an advisory committee on his own initiative. The petitioner as well as representatives of the Department of Health, Education, and Welfare shall have the right to consult with the advisory committee.

The request for referral, or the Secretary's referral on his own initiative, may be made at any time before, or within 30 days after, publication of the Secretary's order acting upon the petition or proposal.

Within 60 days after the referral date or within an additional 30 days if necessary, the advisory committee shall certify to the Secretary a report and recommendations. Within 30 days after such certification, and after giving due consideration to all the information before him, including the report, the Secretary shall by order confirm or modify any order theretofore issued, or if no such prior order has been issued, he shall by order act upon the petition or other proposal.

Where by reason of section 706(b) (5) (B) the Secretary has initiated a proposal to remove from listing a color additive previously listed and a request has been made for referral of such a proposal to an advisory committee, the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations and he has considered such recommendations unless the Secretary finds that emergency conditions exist necessitating the issuance of an order.

The committee intends by the term "emergency conditions" to mean, in general, a condition which requires immediate action in order to avoid imminent hazard to public health.

The advisory committee shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background. In the unlikely event that the National Academy of Sciences is unable or refuses to act, the Secretary shall select the members of the advisory committee. The size of the committee shall be determined by the Secretary.

Any report, recommendations, underlying data, and reasons certified to the Secretary by such advisory committee shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C. 1006 (c))—page 18, beginning on line 11 of reported bill.

The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing—page 18, beginning on line 17 of reported bill.

Fifth. Color additive deemed to be safe under the proviso in section 706(b) (4) need not be certified—page 17, beginning on line 5 of reported bill. This committee amendment provides that any color additive which has been listed as suitable and safe for use generally in or on food by reason of the proviso in proposed section 706(b) (4), discussed above, need not be certified by the Secretary under proposed section 706(c) in this bill.

Sixth. Time schedule governing action on a petition—page 17, beginning on line 21 of reported bill. This committee amendment sets up a time schedule governing the action on a petition to the Secretary for the issuance, amendment, or repeal of a regulation, except where matters are referred to an advisory committee. As stated above, a separate time schedule is prescribed for cases involving advisory committees.

Notice of the proposal made by a petition must be published in general terms by the Secretary within 30 days after filing, and the Secretary's order acting upon such proposed shall be issued within 90 days after the date of the filing of the petition. The Secretary may extend the 90-day period up to but not exceeding 180 days as he deems necessary to enable him to study and investigate this petition. This is the same time schedule as is provided in the Food Additives Amendment of 1958.

Seventh. Review of regulation by Secretary terminating or placing a tolerance limitation on a provisional listing—page 26, beginning on line 7 of reported bill. This committee amendment provides that if the Secretary of Health, Education, and Welfare has, by regulation issued pursuant to the transitional provisions of this legislation, terminated a provisional listing (or deemed provisional listing) of a color additive or a particular use thereof, or if he has established, or made more restrictive, a toler-

ance limitation or other restriction or requirement with respect to an already effective provisional listing, any person who may be adversely affected by such action may petition the Secretary for an amendment to revoke or modify such action, but such petition will not operate to stay or suspend the effectiveness of such action. The Secretary must afford all interested persons an opportunity to present their views on the proposal of the petition after which the Secretary shall act on the petition by published order.

Any person adversely affected by this order may, within 30 days, file objections thereto, state reasonable grounds therefor, and request a public hearing upon such objections which shall be granted. Based on the evidence adduced at such hearing, the Secretary shall issue an order which may reinstate a terminated provisional listing or alter a previously established temporary tolerance limitation, or alter any other limitation established by him, only if in his judgment the evidence shows that such action will be consistent with the protection of the public health. Such order shall be subject to judicial review in accordance with section 701(f) of the Federal Food, Drug, and Cosmetic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. The court may not stay or suspend the Secretary's order pending conclusion of judicial review.

Mr. Speaker, there is no opposition that I know of to this bill. As I have stated, there are differences of opinion on the Delaney anticancer clause. Of course, we are all opposed to this great and dreaded disease of cancer. No one with any forethought would dare to advocate the use of any cancer producing substance that would endanger the health of the people of this country. That is the only provision in this bill that brings about differences of opinion.

It is true that the Secretary of Health, Education, and Welfare did say if we did not have the Delaney clause in the bill—and I here want to join others in complimenting the gentleman from New York [Mr. DELANEY] for his consistent and determined effort toward this great problem—he would administer the law the same as if the Delaney clause had been written into it. The Secretary did have this provision in the bill when he sent it up to the Congress and asked me to introduce it. The Secretary testified he thought it should remain in the bill because he did not believe that he as Secretary or any administrator at this time should have the authority to make a determination permitting the use of any substance known to be cancer producing.

The SPEAKER pro tempore. The time of the gentleman from Arkansas has expired.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent to proceed for 5 additional minutes.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

Mr. HARRIS. Mr. Speaker, the Secretary did that on the basis of information or advice, he said, he received from his own scientists in the National Institutes of Health and in the National Cancer Institute to the effect that we do not know scientifically enough about the subject of cancer at this time to grant discretion to someone to set safe tolerances for known carcinogens. The committee considered it and we felt that under the circumstances it would be best at this time to include the Delaney provision in the bill.

We tried to meet that problem and I think in conference, if we get to conference—the Senate may pass this without a conference, I do not know—but if we get to a conference this and other amendments made by the committee will be subject to consideration.

Mr. Speaker, I have tried to explain this so the House will know what is involved in this problem. I urge the House to pass this bill.

Mr. Speaker, I have two amendments to the committee bill.

The first amendment is a technical amendment, made necessary by the passage by the other body of H.R. 7480, which added a new subsection (1) to section 403 of the Federal Food, Drug, and Cosmetic Act.

The bill (H.R. 7624) currently under consideration proposes to add a new subsection (1) to the same section 403. This amendment corrects the subsection designation to "(m)."

The second amendment is a technical amendment, which makes no change in the intended policy of the bill. It also is made necessary by a recent amendment to the law.

On Saturday, June 18, 1960, the other body passed and cleared for the President, H.R. 7847, which amended section 409(g) (2) of the Federal Food, Drug, and Cosmetic Act by adding a new sentence to that section.

The bill (H.R. 7624) currently under consideration cross-refers to the third sentence of such section 409(g) (2). The enactment of H.R. 7847 will render this cross-reference incorrect; therefore, this amendment—correcting the cross-reference—is necessary.

I would like to include as part of my remarks, a letter dated April 21, 1960, from the Secretary of Health, Education, and Welfare commenting on the various amendments proposed by certain witnesses who testified on this legislation before the committee. This letter was inadvertently omitted from our printed hearings:

DEPARTMENT OF HEALTH,
EDUCATION, AND WELFARE,
Washington, D.C., April 21, 1960.

HON. OREN HARRIS,
Chairman, Committee on Interstate and Foreign Commerce, House of Representatives, Washington, D.C.

DEAR MR. CHAIRMAN: On January 29, you indicated during the hearings on pending color additive legislation (H.R. 7624, and S. 2197) that you would like to have our views on the various amendments proposed by witnesses other than those representing this Department. Accordingly, we have reviewed the record of the hearings and are glad to offer the following comments.

The amendments proposed by the witnesses fall into four principal categories:

1. There are a number of suggestions for change in the scope of the bills.

2. There are several recommendations with respect to the substantive criteria for listing colors, including a number of adverse comments on the anticancer clause in the Department's proposal as contained in H.R. 7624. The criticisms of the bill's anticancer clause also extend to the clause from which it is derived, i.e., the so-called Delaney proviso in the Food Additives Amendment of 1958.

3. A number of suggestions are made on procedural points, both with respect to the permanent part (title I) and the transitional part (title II) of the bill.

Additionally, one individual, Mr. Frank Schell, of Florida, has written to the committee proposing an entirely new bill to be substituted for the Department's bill.

Our comments on these various items, except the anticancer clause are enclosed herewith (enclosure I). I expect to testify further on the anticancer clause. There is enclosed herewith (enclosure II) a draft of a provision which would accord an opportunity for hearing with respect to certain regulatory actions under the transitional part of the bill, under the conditions stated in my testimony. There is enclosed (enclosure III) a draft amendment to the proposed section 706(d) of the bills, to incorporate time limits in the rulemaking procedure of the legislation if the committee should wish to do so. Also there is enclosed (enclosure IV) a draft amendment to section 203(d)(2)(A) of the bill to make it clear that funds and regulations dealing with the cost of certifying coal-tar colors under section 706 of the basic act, shall continue to be available and in effect, respectively, for the purposes specified in section 706 as amended by the proposed bill.

In summary, we are opposed to all the amendments proposed by the witnesses, except (1) a clarifying amendment on agricultural chemicals, in the form contained in enclosure I agreed upon by us with the Department of Agriculture, and (2) the amendments set forth in enclosures II and III. As between the respective versions of S. 2197 and H.R. 7624, we have already advised that the changes contained in S. 2197 as passed by the Senate are acceptable to us, except that we recommend inclusion of the anticancer clause of H.R. 7624 with a modification relating to animal feed similar to the one we are developing for the Delaney proviso to the Food Additives Amendment of 1958. We have also recommended, by letter dated April 11, 1960, a technical correction in section 706(d).

Sincerely yours,

ARTHUR S. FLEMMING,
Secretary.

ENCLOSURE I

COMMENTS ON AMENDMENTS TO S. 2197 OR H.R. 7624 PROPOSED BY NONGOVERNMENTAL WITNESSES

I. SCOPE OF BILL

1. Nature, source, or type of action of the coloring material

(a) Artificial or Natural Colors

Two witnesses suggested that the bill should apply only to artificial colors. There is, in the first place, no sound scientific basis for the distinction between artificial and so-called "natural" colors. In the second place, this proposal, in our opinion, would have serious consequences if adopted. It would raise, with respect to each color, a question of semantics and chemistry, i.e., what is an artifice and what constitutes artificial coloring, which would tremendously complicate the administration of the bill. The preparation of almost any color involves some artifice; even the commercial removal

of natural color from a plant involves artifice. There appears no good reason why the administration of the color additive bill should be needlessly complicated by opening up a tremendous field for argument as to what colors are or are not artificial.

Ultimately, the proposal, if adopted, would prevent the establishment of complete lists of safe colors suitable for use in foods, in drugs, or in cosmetics, and would thus eliminate one of the desirable goals of this legislation which would be useful to the industries concerned.

The suggestion of one industry representative that any material which is directly derived from a vegetable or animal source be excluded from coverage, is similarly objectionable.

(b) Agricultural Chemicals

Several witnesses suggested that pesticide chemicals be exempted from the coverage of the color additives legislation. A representative of the National Agricultural Chemicals Association, on the other hand, indicated that the Department's position as to the interpretation of the bill—i.e., that chemicals affecting color of fruit or other produce merely through their effect on plant metabolism do not "impart color" within the meaning of the bills—as submitted in our letter of February 8, 1960, to you, would meet the needs of the association. However, by letter, the association has, we understand, requested that this position be incorporated in the language of the bill rather than left to legislative history. The Department of Agriculture also favors this. We have no objection to incorporating the position in the bill itself and suggest that the following language—jointly developed by this Department and the Department of Agriculture, and submitted to the committee by that Department by letter dated April 14, 1960—be added as subparagraph (3) to the definition of the term "color additive":

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil, or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

More sweeping language suggested by the association and some other witnesses, which would mandatorily exempt a pesticide chemical even though that chemical also acts as a dye would be seriously objectionable since it would result in our list of food colors being incomplete and would admit of circumventing the certification provisions of the bill through the development of combined pesticide-dye chemicals. We invite attention to the fact that the bill already excepts from the term "color additive" any material "which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring."

(c) "Food Additives"

The bills would amend the term "food additive" as defined in present law so as to exclude "color additives," thus making the definitions and operative provisions mutually exclusive and treating all coloring materials under one special scheme of regulation.

Two witnesses suggested that so-called food additives should be exempted from the bills. This proposal, if adopted and taken at face value, would destroy the color bill insofar as foods are concerned. At present, coal-tar colors are excluded from the food additives amendment by implication because they must be "harmless" substances and no safe tolerance may be granted for them. (They are also excepted from the present definition of "food additive" by sec. 201 (s)(3) if they are still listed as coal-tar

colors under a listing antedating Public Law 85-929.) To repeal the coal-tar color sections of the present law and enact legislation embodying this proposal would mean that all coal-tar colors employed for food purposes would fall within the definition of food additives and thus would be relieved from the batch certification provisions of the present law and the proposed legislation. Not even the manufacturers of coal-tar colors wish this. On the contrary, they have indicated to us that they desire continued certification of colors and would not welcome legislation that failed to permit it. We believe that continuation of the certification system for certain colors is a desirable public-health procedure. Certification insures the composition and purity of substances which must be manufactured with extraordinary care to avoid serious errors.

If, on the other hand, the above-mentioned proposal is intended to mean that all food additives except the so-called coal-tar colors should be exempted from the bills, thus limiting the coverage of bills with respect to food colors primarily to the so-called coal-tar colors, the proposal is objectionable on the grounds that the distinction is not scientifically sound from the point of view of determining the safety of a color, that certification may be desirable for public health protection in the case of some non-coal-tar colors where a tolerance limitation is necessary, and that the proposal would frustrate the valuable objective of a comprehensive list for food colors.

Another witness suggested that substances already cleared under the Food Additives Amendment should be exempt from the color bill. This suggestion, if adopted, would also prevent the desirable preparation of one complete list of colors safe and suitable for use in foods. To the extent, if any, that colors may have been formally cleared as "food additives" by the time this legislation is enacted, the Department will list them under the bill on its own initiative, thus imposing no further procedural burden on the industries concerned.

2. Purpose for which a dye material is used (a) In General

Some witnesses suggested that colors should come within the definition of "color additive" only if they are added or applied primarily for the purpose of imparting color. Such a change in the bill would in our view be objectionable because (1) it would be a large backward step as compared to the present law governing listing and certification of colors; (2) it would make the listing of color additives incomplete—thus confusing users of colors and making separate provisions for food color additives pointless—and (3) it would cast a heavy and unjustifiable burden on the Government in administration and enforcement of the law.

Under present law, a coal-tar color, as defined by regulation, is a material (of certain chemical characteristics) which, when added or applied to a food, drug, cosmetic, or the human body, is capable of imparting color thereto. The purpose for which the material is so used is irrelevant under that definition, although, under the substantive provisions of the act relating to drugs, the drug is subject to the color certification requirement only if the material which imparts color is used in or on the drug solely for that purpose. The present bills follow this approach with respect to color additives (including the special provisions as to drug colors), except that, as stated under point 1.b. of this memorandum, the bills exclude from the definition any material which the Secretary, by regulation, determines is used (or intended to be used) solely for non-coloring purposes.

It is not entirely clear whether the purpose-of-use amendment proposed by the witnesses is intended to refer separately to

each use of a color on a particular article, or to the primary purpose for which the material is being used by a particular industry or processor (e.g., a food industry or processor), or some other criterion of purpose. Different witnesses may have had different things in mind in making the suggestion.

In any event, however, to adopt this proposal would create a very difficult, and perhaps impossible enforcement problem. The Government would have the responsibility with respect to each use, or each listing, of a color to determine whether the color effect that it contributed was purposeful and, if so, whether the achievement of that effect was a primary or secondary purpose in the use of the color, and in addition the Government would have to assume the burden of proof that its determination of primary purpose was correct. This would lead to a situation in which no one could determine with any degree of certainty whether or not colors that serve some other incidental purpose are, in fact, subject to the amendment. An example of the difficulties that would arise is furnished by the yellow color beta carotene. Beta carotene is not only used as a coloring agent but also is broken down in the human body to form vitamin A. If the proposal in question were adopted in the sense in which it is probably intended, then, before the Government could determine whether the carotene were a color additive, it would have to determine, and be prepared to prove, whether the primary object in the manufacturer's mind was to increase the vitamin A content of the food or to produce a deeper yellow color. Some batches of the color might be subject to the amendment and others exempt. This would not be a desirable situation.

We therefore believe that the bill should remain unchanged as regards the question of the relevance of the purpose for which a coloring material is intended.

(b) Colors in Food Packaging Materials

Our letter of February 8, 1960, which has been introduced into the hearing record, makes clear that coloring materials used in food wraps and other food packaging materials are not within the purview of the bill if the coloring material does not migrate from the wrap to the food or if, though there is some migration, it is so slight that it does not impart to the food any color apparent to the naked eye.

A representative of one part of the packaging industry, however, requests that colors for packaging materials be exempted unless they are by design intended to add color immediately from the wrap into or on food, thus casting on the Government the difficult burden of proving such intent. We question the wisdom of adopting this proposal. The purpose of the color additive amendment is to establish a class of colors suitable for use in foods (or drugs or cosmetics) so that users will no longer have any question about whether the products they use are suitable. The bill would, as above stated, allow the Secretary, by regulation, to exempt from its coverage any material which he determines is used or intended to be used solely for a purpose or purposes other than coloring food (or drugs or cosmetics). This provision would give the Department the authority to relieve from coverage of the legislation those substances not used for food coloring, and this, we believe, is as far as they should be exempted. To go any further and relieve from coverage of this bill substances that are added to packaging materials with the intent of imparting color later to food products packaged therein would, in our opinion, seriously weaken the bill and would be contrary to its main purpose, which is to provide for the same type of coverage for all

color additives. Therefore, we must recommend against inclusion of this suggestion.

(c) Other Incidental Additives

One witness suggested that all colors which are incidental additives—presumably to food—should be exempt. An "incidental additive" to food, as we understand the term, is an additive which is not used for the purpose of becoming a component of food or affecting its characteristics but the intended use of which in connection with food production, manufacture, handling, etc., may nevertheless reasonably be expected to, and actually does, have that result. (Cf. sec. 201(s) of the basic act.)

One type of such incidental additive, i.e., migratory colors in food packaging materials, has been discussed above. As pointed out in that connection, the bills already would permit the Secretary to exempt any material which he determines is used solely for a purpose or purposes other than coloring. As above stated, we believe that it would be a mistake to go any further in providing for exemptions from the scope of the bill.

3. Substances generally recognized as safe

Certain witnesses suggested that substances which are generally recognized by experts as having been shown to be safe be excluded from the definition of "color additive" and thus from the coverage of the proposed legislation. This suggestion has been coupled, at least by some, with the suggestion that this general recognition should, in analogy to the "food additive" definition of the basic act, be allowed to rest either on scientific evidence or on experience based on common use of the color. The proposal is unacceptable for several reasons.

In the first place, as pointed out above, a major purpose of the bills is to establish comprehensive lists of food, drug, and cosmetic colors, with assurance to users that the colors are both safe and suitable for the use or uses for which they are listed. The proposed amendment to the bills would destroy this assurance for the user and establish a broad area of indecision in which the user of colors would not know whether the materials he expects to employ are acceptable under the Food, Drug and Cosmetic Act. Where a color additive is in fact generally recognized as safe by appropriately qualified experts, there would be no difficulty in listing it for such safe use.

In the second place, such an amendment would open the door to the contention, however unsound, that all or some of those coal-tar colors which are at present listed as "harmless," and are not "delisted" before enactment of the bill, have thereby, or through experience based on common use, become generally recognized as safe, even though in the opinion of this Department the "harmlessness" of many of them is at least suspect and their safety for given uses remains to be scientifically determined. Under the proposed amendment to the bills, moreover, this issue, if raised, would have to be tried out in the courts de novo. This consideration in itself is enough to call for rejection of the amendment.

Finally, it should be emphasized that, even if an exemption were to be considered for colors generally recognized as safe, it would not be appropriate to cast it in the form of an exclusion from the definition of the term "color additive," for the question of what is a color additive cannot rationally be made to depend on whether the additive is generally recognized as safe. The only reason for excepting colors "generally recognized as safe" from the definition itself would be to cast on the Government the burden of proof to satisfy a court, de novo, that a particular color is not generally recognized as safe instead of casting the burden on the proponent of a particular color use to establish its safety in proper rulemaking proceedings. As

said by us in submitting the proposed legislation to Congress:

"While there may have been justification in the case of the Food Additives Amendment of 1958 for placing the burden on the Government to prove that an additive is not generally recognized as safe before the safety clearance procedure applies—in view of the broad sweep of the amendment, which otherwise would have covered such additives as salt, vinegar, and natural spices—we do not believe that such an exception is sound in the case of color additives, whether they be extracted from a natural source or synthesized. To engraft such an exception on the bill would be retrogressive as compared with present law relating to coal-tar colors. If a color is in fact generally recognized by competent experts as safe for unrestricted use in any kind of article, this can be readily established and reflected in regulations listing such color."

As indicated in the Secretary's testimony, however, we are agreeable to the provisos added in the Senate to S. 2197 (p. 9, lines 12-19; p. 12, line 24, down to p. 13, line 13), whereby a food color additive is deemed suitable and safe for listing purposes and is entitled to exemption from the requirement of certification, while there is in effect a published finding of the Secretary declaring the substance exempt from the term "food additive" because of its being generally recognized by experts as safe, as provided in section 201(s) of the basic act. It should be noted that in such cases the substance is still to be listed, rather than exempt from listing, as a color additive.

II. SUBSTANTIVE PROVISIONS AS TO LISTING OF COLORS (SEC. 706)

1. Basic provision for listing

One witness suggested that the proposed section 706(b)(1) be amended to require that the Secretary (by regulation) shall "separately list," rather than "provide for separately listing," color additives. The phrase in section 706(b)(1) was modeled after sections 406(b), 504, and 604 of the present act which require "regulations providing for the listing" of coal-tar colors. Other paragraphs of the proposed section 706(b), however, already use the more direct phrase "regulations may list" or "the Secretary shall not list." Both section 706(b)(1) in its present form and the suggested modification thereof contemplate listing by regulation and, insofar as we can determine, there is no practical difference intended between the two versions. The Department could operate equally well under either provision, if it is clearly understood that the Secretary may not and will not merely list colors by regulation, but, necessarily, also promulgate interstitial regulations providing for the listing, i.e., relating to the conditions and procedures for such listing, interpretations of the law, etc.

2. Analytical methods requirement

One witness has suggested that the bill should not require an analytical method for determining the identity of the color additive if it has been mixed with other ingredients. The coal-tar color regulations now require this (21 CFR 9.14). If this proposal is intended to mean that the Department should approve a color which is so toxic that the quantity employed must be limited, without having any mechanism for determining, after it is used, whether the safe level has been observed or exceeded, we must oppose the suggestion. The amendment we have agreed to (p. 10, lines 14-20, of S. 2197) is a relaxation of the requirement in the food additives amendment that a practical method of testing for an additive be available for any substance formed in food because of its use. The amendment in the Senate version of the color bill requires a practicable method of analysis only where

it is needed, i.e., where there is some enforcement purpose to be served by having the method.

The proposal that we be deprived of the right to require an analytical method for determining the identity of an additive once it has been used, could, if adopted, also be interpreted to deprive us of the opportunity of requiring suitable methods for the quantitative determination of an additive since it is necessary to know the identity of a chemical in order to determine its quantity.

It would be poor public-health policy to allow toxic materials to be used in foods, drugs, and cosmetics without any mechanism for checking upon their quantity to be sure that they are present in nonharmful amounts.

3. *Intended-effect requirement (sec. 706(b)(7))*

Several witnesses testified that the industry should not be required to show that a toxic color will achieve its intended physical or other technical effect in order to get the color listed as acceptable for use. Some view this requirement as a type of "functional value" test.

The injection of the so-called functional value issue here is based on a misunderstanding of the bill. There is nothing in the bill that would undertake to tell a beverage manufacturer, for example, that he could color his lime beverage only to a tint which the Secretary considered desirable. Instead, the bill—following the pattern of the Food Additives Amendment of 1958 (sec. 409(c)(4))—says that the Department shall not establish a tolerance for a toxic color higher than reasonably required to accomplish the intended physical or other technical effect. The beverage manufacturer would decide what degree of coloring was needed to accomplish that effect and the Department could deny the requested tolerance only on a finding that it was not shown to be safe, or that the desired degree of coloring could be obtained without using this quantity of color. (And of course the use would have to be denied if it would result in violation of some other section of the law).

This bill—still following the cited provision of the Food Additives Amendment—also provides that where the amount of color that can be safely tolerated will not achieve the intended physical or other technical effect, no tolerance for this use should be permitted. For example, if because of its toxicity we can only allow 3 parts per million of a yellow color intended for use in coloring margarine and 40 parts per million were required to impart to the margarine the desired degree of yellow, there would be no point in establishing a safe tolerance of 3 parts per million which would leave the margarine white. On the contrary, to establish a tolerance which would not achieve the intended effect would invite widespread violation of the tolerance limitation.

The requirement that a toxic color should be found capable of achieving its intended physical or other technological effect before it is allowed for use is designed to permit the Secretary to make each decision as safe as possible. The Food Protection Committee of the National Research Council has summarized the problem concisely in its pamphlet entitled "Principles and Procedures for Evaluating the Safety of Intentional Chemical Additives in Foods." On page 2 of the pamphlet (November 1954 issue), the second general principle which it lists is: "Results of critically designed tests of the physiologic, pharmacologic, and biochemical behavior of a proposed additive made in various species of animals can provide a basis for the evaluation of the safety of a chemical additive at a specified level of intake by man. It is impossible, however, to establish absolute assurance that the additive at this level will be completely safe for all humans under all conditions."

Clearly, so long as it is impossible to establish absolute assurance of safety, it is imperative to restrict the purposeless addition of toxic substances to the food supply (and to drugs and cosmetics).

Moreover, consistency between this part of the bills and the corresponding provisions of the Food Additives Amendment is also important inasmuch as a food color additive will not necessarily be used solely for the purpose of coloring, but may also be marketed and used in food to achieve another, no less important, effect.

4. *Requirement of suitability for intended use*

Other witnesses have objected to the use of the term "suitable" in the proposed section 706(b)(1) of the bill, a term taken over from the coal-tar color provisions of existing law where it is used in the same sense. They believe that the Secretary should rule only on safety and not on what they consider to be economic factors. The need for authorizing the Secretary to sanction only those colors that are suitable may be illustrated by listing some examples of use that would be unsuitable:

An unstable color that faded before the food in which it is used could reach the consumer would be unsuitable.

A color that would not stay in solution would be unsuitable for coloring liquids.

A diluent used to make a color mixture for food use that would adulterate or cause other adverse changes in food would be unsuitable.

Plainly, having by law been concerned with color suitability even where the color was required to be a completely harmless substance, we should continue to exercise some power of control over situations of this type in determining whether colors, which under the bill could be toxic materials, may be incorporated in the food, drug, or cosmetic supply.

It is difficult to follow the reasoning of the witnesses because, as above stated, the requirements of suitability appears in the color sections of the present law and has been there since 1938 when the Food, Drug, and Cosmetic Act was enacted. If there is any serious problem occasioned by the use of this word, we are not aware of it and the witnesses themselves have not cited any real problem. The certified color industry, which is familiar with the way the present law has worked, has raised no question about this provision of the bill.

5. *Prohibition against listing for illegal deceptive color uses*

Some witnesses have argued that the Secretary should have no power to decide whether use of a color would promote deception of the consumer. And one witness would amend the term "deception" to read "harmful deception." They appear to overlook the fact that the bill is more specific than this. It provides (sec. 706(b)(6))—following again the pattern set by Congress in the Food Additives Amendment of 1958—that "The Secretary shall not list a color additive * * * if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act."

Again there appears to be some misunderstanding of the purpose of the bill. This particular provision is intended to make it perfectly clear that the Department could not be placed in a position where it would be required to authorize under one section of the law a practice that would be illegal under another section; it is inconceivable the Congress would want such a situation to exist. And if it was appropriate to make this clear in a general food additive law, it is at least equally so in a color bill.

To avoid any misunderstanding, we emphasize that the Department has no objection

to the artificial coloring, under proper labeling declaration, of mature oranges. We have given this assurance to the citrus industry, we have stated it for the record at the hearings on the present bills, and we repeat it here.

But there are coloring practices that would promote deception in violation of the basic statute and we believe that the bill should make clear that these would not be allowed. Examples are:

(a) The use of artificial color in egg noodles to hide a deficiency in eggs.

(b) The use of artificial color on immature apples or oranges to make the fruit appear to be mature.

(c) The use of artificial color in tomato catsup or juice or canned tomatoes prepared from immature raw material.

(d) The use of artificial color in stale red meat to make it appear fresh.

We could not accept an amendment which would seem to say that we are required to approve a practice under one section of the law which in our opinion would constitute a violation under another section and would call for prosecution if it were followed.

6. *Allocation of listings or of aggregate tolerances*

Some of the industry witnesses object to giving the Secretary the authority contained in the proposed section 706(b)(8) of the bill, i.e., authority to allocate color uses where safety factors will not permit a color to be employed for all uses proposed and at the levels proposed. When stripped of extraneous trappings, these arguments boil down to an unwillingness on the part of some firms to compete for a color on the basis of the effect of the color on the marketability of their products, the availability of satisfactory substitute colors, and other relevant factors. In other words, everybody seems to want the opportunity of using the particular color he happens to decide upon in the amount he wishes to employ in his products. But inevitably a situation will arise in which the allowable safe tolerance of a toxic color will not permit all of the uses desired. When such a situation arises, we could:

1. Deny use of the color to everyone—an impractical approach which no one argues for.

2. Allocate the color on a first-come first-served basis—again an impractical approach because this could allow the first manufacturer who requested use of a color to arrogate to his product the total allowable tolerance for that color even though it were not a major factor in the acceptability of his product and even though adequate substitutes were available which would accomplish the same purpose for his product.

3. Establish a reasonably practical system, as proposed by the bill, for allocating the amount of color, where safety will not allow granting of all uses requested among the competing industries. It seems obvious to us that there may have to be allocation, particularly for some colors already in use. The question is under what guidelines and by whom?

The allocation proposal suggested in the bill is one that our Department developed in cooperation with the Certified Color Industry Committee and representatives of certain other industries. It sets forth guidelines within which the Government must operate. It is the best proposal we have been able to develop. The alternate proposals made by industry witnesses would remove these guidelines in whole or in part and, as we see it, leave the Government subject to fewer checks.

The problem here is peculiarly an industry problem. While we question the adequacy of some of the proposals made by the industry witnesses, we are not prepared to make a major issue of this point. We do request the committee to give us, in as

much detail as possible, the guidelines to follow when allocation does become necessary.

III. PROCEDURAL CHANGES UNDER PERMANENT PART OF BILL (SEC. 706(D))

1. Referral of safety questions to an outside scientific group

One witness testified that a commission or outside committee of scientists should be established to resolve questions of safety. It is not clear from his testimony, including his answers to questions raised by some members of this committee, what type of outside advice he would like the Department to receive. And some members of the scientific panel also favored specific provision for a panel of outside experts. We have no need for such a provision since we are already empowered to consult scientists outside the Department, and do so frequently. If industry wishes to have in the color additives bill provision for difficult questions to be referred to ad hoc scientific committees for study and the issuance of advisory recommendations we would not object.* Of course provision would have to be made in such event for extending appropriately any time limits placed on the Department's actions under the bill. In fact, we included such a provision in the Department's draft of food additives legislation which was considered by the last Congress (H.R. 6747, 85th Cong.), but this was deleted at the strong urging of some elements of the food industry itself.

But we would be vigorously opposed to a requirement that all scientific decisions on color additives would have to be submitted to an outside group of scientists for review. This would make an impossible administrative situation, with the result that the law could not be put into practical effect in the foreseeable future. It is, moreover, essential that the agency responsible for administering this law have the authority to make decisions under it.

2. Time limits for action on petition

One witness suggested that the procedure for action on a petition specified in section 706(d) of the bill be modified by requiring that notice of the proposal contained in the petition be published within 30 days and that the Secretary be required to act on the petition within 90 days (with the privilege to extend this period for another 90 days), as is now required in the procedure for food additives. As the witness recognized, such a provision would not necessarily be of advantage to a petitioner if the time for informed and considered action in a particular case is inadequate. We would, however, have no objection to the insertion of such time limits. A draft of appropriate language is enclosed (Enclosure II) for the convenience of the committee if it should decide to adopt the suggestion.

3. Scope of judicial review

The bills in their present form incorporate by reference those provisions of the Food Additives Amendment of 1958—i.e., section 409(g) of the Federal Food, Drug, and Cosmetic Act—which require that the Secretary's order after public hearing "shall be based upon a fair evaluation of the entire record at such hearing," and that, on judicial review, the court of appeals may sustain the Secretary's order and findings only if "based upon a fair evaluation of the entire record." One witness has recommended an amendment which would combine those requirements with still others by providing as follows:

"(1) The Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be based upon the preponderance of the substantial probative evidence and upon a fair evaluation of a full, true, and correct record, and shall include a statement setting forth in

detail the findings and conclusions upon which the order is based, and

"(2) the scope of judicial review of such order shall be in accordance with the judicial review provisions of section 409(g), except that the rule for judicial review shall be that the findings of the Secretary with respect to questions of fact shall be sustained only if based upon the preponderance of substantial probative evidence and upon a fair evaluation of a full, true, and correct record and the Court upon such judicial review shall not sustain the order of the Secretary if he failed to comply with these requirements."

The witness did not appear disposed to press the amendment, and brief comment on it should suffice. The amendment is seriously objectionable in that it is admittedly designed to authorize, indeed require, the courts of appeals to go further in reversing the Department's judgment on safety in the case of color additives than would be allowed in the case of food additives, and would inject the courts into quasi-legislative policy involved in rulemaking instead of confining them to passing on the validity of the rule. It would vest in reviewing courts broader powers of review than are exercised by them in the review of the findings of fact of trial judges and would disregard the greater expertise of the regulatory agency in its specialized field.

The committee will recall the many steps in the development of the rule for judicial review that was incorporated finally in the Food Additives Amendment of 1958, after the Subcommittee on Health and Science had received a wide range of proposals as to the scope of judicial review, including one which would have permitted the reviewing court to set aside the Secretary's findings unless "supported by the weight of the evidence in the record as a whole." Commenting on that proposal, Assistant Secretary Elliot L. Richardson, testifying on behalf of the Department, said:

"This would seem to call upon a court to substitute its own judgment for that of the expert administrative agency on questions of the relative weight of conflicting evidence, including, as would be likely in these cases, the relative weight of fairly conflicting views and opinions of scientific witnesses, and then to sustain or strike down the findings of the Department depending on whether they are in accord with the weight of the evidence on the court's own scales.

"This, I believe, would be objectionable for largely the same reasons as a completely de novo proceeding."

We believe that the rule evolved by the committee for the food additives amendment and incorporated in the color additive bills is a reasonable one and should at least be given a fair trial before the committee entertains proposals to adopt new language of uncertain meaning. It was not claimed at the hearings on the color bills that the broader scope of judicial review now urged is needed particularly for color additives or, for that matter, for other formal rulemaking decisions under the Federal Food, Drug, and Cosmetic Act. On the contrary, the witness stressed that the amendment was not aimed primarily at this Department but was offered, on behalf of his principals, as "a good formula for administrative review generally." It should go without saying that a regulatory law for consumer health protection is not the place to experiment with general reforms in the field of judicial review of quasi-legislative administrative action, especially when the experiment would, as here, require the judiciary to substitute its judgment for that of the expert regulatory agency as to the weight of the scientific evidence.

In essence, this proposed amendment would seem to require the court of appeals to weigh the scientific facts on which the

Department's judgment on the safety question is based, and in effect to make a policy decision as to the future safety of the use of the proposed color additive in the Nation's food, drugs, and cosmetics. It will be recalled that Chief Judge Biggs of the third circuit, testifying on the food additives bills in the last Congress, and Chief Judge Stephens of the District of Columbia circuit, testifying on the original version of the pesticide chemicals bill in the 83d Congress—in the context of proposals for de novo review by the courts—both expressed the carefully considered view of the Judicial Conference of the United States that it is unwise to assign to the courts responsibilities for making policy decisions of this kind. Yet this, in effect, is precisely what would be required by the amendment proposed by this witness. We believe, therefore, that, as proposed in the color additive bills, the food additives amendment should be followed on this point.

With respect to the agency's own function in evaluating the evidence, likewise, the proposed amendment should, we believe, not go beyond the provisions of the food additives amendment as adopted (by reference) in the pending bills. In this connection, attention is invited to the fact that under section 7 of the Administrative Procedure Act, which applies, we could not issue a regulation on a color additive except "in accordance with the reliable, probative, and substantial evidence" upon consideration of the whole record or such portions of it as may be cited by any party. That section also adequately defines the term "record."

IV. CHANGES IN TRANSITIONAL PART (TITLE II)

1. Proposals for formal hearing and judicial review with respect to adverse action to provisional listings

Two witnesses, but not the spokesmen for the certified color industry, urged the committee to insert in the transitional part of the bills (title II) provisions for formal hearing procedures and judicial review like those contained in the permanent part (title I, section 706(d)). One of these witnesses seemed to limit this recommendation to cases in which the Secretary, acting under title II, has terminated a provisional listing which had previously been established by him or which had automatically been established by the legislation itself.

In making this recommendation, one of the witnesses made the rather startling contention that in the absence of such provisions the transitional part of the bill would be unconstitutional. While he did not state the ground for this contention, presumably he was referring to the due process clause of the fifth amendment. The contention is without substance since the actions of the Secretary under title II of the bills would be regulatory (i.e., quasi-legislative) rather than adjudicative in character, and since the Constitution no more requires hearings for the issuance of such regulations than it does for the enactment of the act of Congress of which such regulations would be but an extension.

As said by the late Harold M. Stephens, chief judge of the U.S. Court of Appeals for the District of Columbia Circuit, in a carefully prepared statement submitted by him in connection with his testimony on H.R. 4277, 83d Congress: ¹

¹ H.R. 4277 was the predecessor of the bill (H.R. 7125) which became Public Law 518, 83d Congress, popularly known as the Pesticide Chemicals Amendment to the Federal Food, Drug and Cosmetic Act. The Department opposed H.R. 4277 because of a provision for de novo review in the courts and other defects. We collaborated in the development of H.R. 7125.

"But it is equally clear that the hearing requirement of the due process clause is not applicable to such actions of administrative boards and agencies as are taken in the exercise of their rulemaking as distinguished from their adjudicatory power. *Bowles v. Willingham* (321 U.S. 503, 519 (1914)); *Bi-Metallic Co. v. Colorado* (239 U.S. 441 (1915)); *Willapoint Oysters v. Ewing* (174 F. 2d 676 (9th Cir. 1949)). The action of an administrative agency is adjudicatory in character if it is particular and immediate. It is of rulemaking character when it is general and future in effect. *Louisville & Nashville R.R. Co. v. Garret* (231 U.S. 298, 305 (1913)); *Prentiss v. Atlantic Coast Line* (211 U.S. 210, 226 (1908)). The action of the Administrator made reviewable under H.R. 4277—the promulgation of regulations establishing a tolerance for any poisonous or deleterious pesticide or exempting such a pesticide from the necessity of a tolerance—is of rulemaking rather than of adjudicatory character. The Congress can, of course, require rules to be made after opportunity for an agency hearing, and where it has done so the requirements of sections 7 and 8 of the Administrative Procedure Act, which reflect the due process clause hearing requirement, are applicable. But in the absence of a specific statutory requirement for an agency hearing in the promulgation of rules, the Congress has provided, in section 4(b) of the Administrative Procedure Act, that in the exercise of rulemaking power an agency shall merely afford interested persons an opportunity to participate in the rulemaking through submission of written data, views, or arguments with or without opportunity to present the same orally in any manner."

The question whether, and if so to what extent and in what circumstances, formal rulemaking procedures and related provisions for judicial review should be introduced into the transitional part (title II) of the bills is thus not a question of constitutional law but of legislative policy. In determining that question, it is important to keep in mind the purposes and provisions of title II, as we did in committing ourselves at your committee's session of January 26, to the introduction (in title II) of appropriate hearing procedures for the review of a termination of a provisional listing by us, provided that the effectiveness of the termination were not stayed in the meantime. Beyond that commitment we are not prepared to go, except for the application of the same approach to the imposition or further tightening of a temporary tolerance or comparable restriction with respect to an already effective provisional listing of a color.

The provisions of this proposed color legislation were developed by the Department only after extended consultation with representatives of the interested industries, and in particular the certified color industry committee which has perhaps the largest, and certainly the most immediate and pressing, interest in this measure on the industry side. The part of the legislation which was the most extended subject of negotiation and consultation was the transitional part.

For example, we were not, at the outset, disposed to permit any provisional listing of a coal-tar color for a use in foods, drugs, or cosmetics where the color had been "delisted" under the old law prior to the enactment of the legislation. After negotiation, however, we agreed not only to the automatic provisional listing of coal-tar colors which had not been "delisted" under the old law, and of non-coal-tar colors which were commercially established before enactment of the proposal, but further to provisional restoration of previously delisted coal-tar colors to the list during the transitional period, provided that we be given broad powers, under summary procedure, to terminate any provisional listing, to refuse to admit to pro-

visional listing a color previously "delisted," and to impose such temporary tolerances (including zero tolerances) and other restrictions as in our judgment we considered necessary for the protection of the public health during provisional listing. Were it not for this discretionary or judgmental aspect of the transitional provisions, it is doubtful that we would have considered submission of the bills as a departmental proposal compatible with our responsibility for the protection of the public health. We believe that the industry representatives with whom we dealt considered this compromise as being very fair, and it will be noted that the certified color industry committee has interposed no objection to title II of the bill.

In the circumstances, we can see no reasonable basis for introducing any hearing requirements into title II with respect to action of the Secretary in refusing to grant a provisional listing for a coal tar color which had been delisted before enactment of the bill, or with respect to the initial establishment of a tolerance or other restriction as an integral part of the Secretary's action in admitting a color to provisional listing, or with respect to establishment of a certification requirement for a coal tar color provisionally listed, or with respect to a refusal to extend the closing date for a particular provisional listing beyond the 2½-year period from enactment of the bill.

Moreover, we could agree to the introduction of hearing procedures and judicial review with respect to other actions under title II only if this is done under careful safeguards which will leave unimpaired our ability to act quickly and effectively for the protection of the public health during the transitional period. In this connection, it must be kept in mind that the transitional provisions of the bills presuppose that those scientific tests and investigations which are necessary to a fully informed judgment as to the instability of a color, and as to the conditions of listing, under the permanent part of the bill have not been completed, and that, in acting or refusing to take action under the transitional part, we must use our best judgment for the protection of the public health on the basis of such concededly incomplete information as is available to us. Plainly, in acting on such a basis, or in defending such action, we could not be expected to carry the burden of proof that we might be expected to carry in revoking a listing, or in setting, establishing, or tightening tolerances or other conditions of use, established under the permanent part of the bill.

Because of this, and in order to preserve the essential power for prompt and effective action under title II, we must insist that any proceeding for setting aside the action we have taken be in the nature of a new proceeding, instituted by an interested person, with the burden of proof on him to satisfy us that such data as we have or as he submits show that the relief he is seeking would be consistent with the protection of the public health, and that in the meantime our action not be suspended.

As indicated in the covering letter, draft language which would amend the bill to the extent to which we would be willing to go is enclosed herewith (enclosure II).

2. Proposal re substantial probative evidence for terminating provisional listings

One witness proposed that section 203(d) (1)(E)—which authorizes the Secretary to terminate forthwith a provisional listing (including a "deemed provisional listing") of a color additive or particular use thereof "whenever in his judgment such action is necessary to protect the public health"—be amended so that the Secretary could take such action only on the basis of "substantial probative evidence." (Insofar as the color in which the witness is particularly inter-

ested—i.e., Citrus Red No. 2, used on oranges—is concerned, the amendment seems irrelevant because, as stated at the hearing, we have all the evidence of safety we need for listing this color under the permanent part of the bill.)

The amendment is unacceptable to us. As above indicated, the whole purpose of the provisional listing plan is, on the one hand, to permit (so far as considered consistent with public health protection) the temporary use of established colors while the scientific tests are being carried forward to completion, and on the other hand—since under the transitional provisions there is admittedly no adequate scientific evidence for definitive conclusions—to allow play for the Secretary's judgment in taking necessarily summary action for protecting the public health on the basis of such data as are available to him. The proposed amendment is designed to frustrate this key element of the transitional plan of the bill. It seems appropriate to add that retention of the present provisions would also make it easier for us to grant a provisional listing in the first place, since we could quickly terminate it if we found that there was a substantial question as to its safety.

As indicated above, however, we would not object to a carefully framed provision for proceedings for restoration of a terminated provisional listing in which the proponent would have an opportunity to present data at a hearing showing to the Secretary's satisfaction that such restoration would be consistent with public health protection.

3. Proposal to delete reference to zero tolerances in section 203(d) (1) (C)

One witness proposed that section 203(d) (1)(C)—which authorizes the Secretary, when necessary in his judgment to protect the public health, to establish "temporary tolerance limitations (including such limitations as zero level)," for provisionally listed colors—be amended by deleting the reference to zero-level tolerances. No reason was given for the proposed deletion. To delete this provision, which had been accepted by the Certified Color Industry Committee and other industry groups consulted before submission of the bill to Congress, would be of no real advantage to the industries concerned because, apart from not preventing a tolerance limitation approaching zero, the deletion would leave intact the power of the Secretary, under section 203(d) (1)(E), to terminate a provisional listing. Under given circumstances, especially where the Secretary's action is intended to be tentative, a temporary zero tolerance might be the more palatable action, at least from the industry viewpoint, than a termination of the listing, even though the prohibition on a particular use of the color is, for the time being, as complete in the one case as in the other. The pesticide chemicals amendment constitutes a statutory precedent for zero tolerance authority (Federal Food, Drug, and Cosmetic Act, sec. 408 (b)). The amendment should, we believe, be rejected.

4. Proposal to delete section 203(d) (3) re tentative zero tolerances in certain cases

Several witnesses—but not those representing the Certified Color Industry Committee—urged deletion of paragraph (3) of section 203(d)—S. 2197, page 20, line 21, down to page 21, line 16; H.R. 7624, page 20, line 19, down to page 21, line 11—on the ground that it would conflict with, or even vitiate, the purpose of the provisions for provisional color listings contained in the preceding part of section 203. This recommendation should be rejected, because section 203(d) (3)—which authorizes the establishment of tentative zero tolerances where those who wish to rely on automatic provisional listings do not furnish us with needed data—is an integral and essential

consumer-protection safeguard of the provisional listing plan insofar as that plan provides for automatic listings.

In the case of those colors for which the bills would automatically grant provisional listings, two types of problem will arise. The first problem is one of determining the identity of these deemed provisionally listed colors, for the benefit of users and for enforcement purposes, a problem which may be difficult where the color is not a so-called coal tar color and hence not readily identifiable through its listing under the old law and regulations. Once a color and its deemed provisionally listed uses have been identified, the second problem is that of establishing appropriate temporary tolerance levels for these uses where needed, and this may make it necessary for us to ascertain the prevailing levels of these uses.

As a partial answer to the first problem, the bills direct us, insofar as practicable, to compile and publish physical lists of colors and their uses which we have found to be in the class of deemed provisional listings and on which users of the color will be entitled to rely. But in order to compile such lists, and in order to ascertain prevailing use levels for these colors as a basis for determining tolerances, we should be entitled to look to the interested industries for the necessary reliable data. Since we lack subpoena power, section 203(d)(3), therefore, would authorize us to establish tentative zero tolerances where such data are not made available to us after interested persons have by public notice been afforded a reasonable opportunity to do so. Where the absence of information is as to the identity of colors or color uses deemed provisionally listed, a zero tolerance with respect thereto might perforce have to be established on a blanket basis. The ultimate net result would be to make the physical lists which we are directed to compile a legally reliable source of information, as regards both inclusion in or exclusion from such lists.

5. Proposal for automatic provisional listings for recently delisted colors

In the case of coal tar colors, the bills (sec. 203(b)(1)) would grant an automatic provisional listing only for uses for which the color was listed and certifiable under the old law "on the day preceding the enactment date" of the present measure. If the color had previously been removed from a list under the old law, it could be provisionally listed under the bills (sec. 203(c)) for such a "delisted" use, but only if, on application, the Secretary were satisfied that this would be consistent with public health protection.

On January 27, 1960, a witness concerned with the "delisting" proceedings now pending with respect to certain coal tar colors which are used in lipstick, urged before your committee that the critical base date for automatic provisional listings be changed from "the day preceding the enactment date" to "January 31, 1960." This change, if adopted, would have the following effect:

A color that had been found not to be "harmless" and therefore had been removed from the list of colors permitted in food or in lipstick after January 31, 1960, and before the date of enactment of the proposed legislation would, as soon as the new legislation is enacted, automatically be provisionally listed for the same uses for which it had earlier been delisted. This would be true even though the studies upon which the delisting action were based failed to establish a safe level of feeding for the color, and even though they had been so abbreviated as to afford no valid basis for determining whether the color would or would not produce cancer when fed. This would create a serious gap in consumer protection. The proposed amendment should be rejected.

In connection with this question, it should here be noted that the witness who proposed

this amendment—Dr. Paul G. Lauffer, speaking for the Toilet Goods Association—was in error when he indicated to the committee that this Department had already conducted the necessary toxicity studies on the lipstick colors that have been proposed for removal from the list of permitted drug and cosmetic colors, which would permit the establishment of safe levels for their use under the proposed bill.

The tests conducted by the Food and Drug Administration on seven drug and cosmetic colors which serve as the basis for the proposed delisting of these and certain closely related colors were short-term tests. They were adequate to show that the colors are not "harmless" as required by present law. They were not extensive enough to show what level of the colors would be safe for ingestion by man.

6. Proposal to cross-refer to title I listings as "official"

In order to mesh the permanent part (title I) and the transitional part (title II) of the bills, the second sentence of section 203(a)(1) provides that a provisional listing of a color additive for any use—including a "deemed provisional listing," i.e., one which is automatic under the bills—shall, if not sooner terminated, expire "on the effective date of a listing of such additive for such use under section 706 of the basic act." (The term "basic act" is defined by sec. 201 as meaning the Federal Food, Drug, and Cosmetic Act, sec. 706 of which, as amended by the present bills, would contain the new permanent provisions for listing and certification of colors.)

One witness suggested changing the above-quoted phrase to read, "on the effective date of official listing of such additive for such use under section 706 of the basic act," on the ground that the characterization of listings under the basic act as "official listings" would help to avoid confusion between listings under the permanent part of the bill and provisional listings under the transitional part. The suggestion should be rejected, first, because provisional listings are also official and, secondly, because the present language, above quoted, is so clear and precise as to preclude confusion on that score.

V. THE NEW BILL

Mr. Frank R. Schell of Tampa, Fla., in his written statement dated January 28, 1960, which was filed with the committee suggested an entirely new bill to replace the color additives amendment. The bill is intended in part to permit the continued use of ethylene as a de-greening agent on oranges. Our Department has already indicated to the citrus industry, to the Senate, and to this committee that this use of ethylene would not be subject to the proposed color additives amendment.

A portion of Mr. Schell's draft bill would substantially amend the food standards section of the present Food, Drug, and Cosmetic Act. The Color Additives Amendment proposed by H.R. 7624 and S. 2197 is not designed to deal with the question of food standards. Amendment of the food standards provisions of the law should, we believe, not be allowed to confuse the questions now before your committee. If food standards amendments are desired, they should be incorporated in a separate legislative proposal under a proper title and the amendment subjected to full hearings at some other time. We are therefore not burdening this report with an analysis of that part of Mr. Schell's draft bill.

And the final portion of the bill proposed by Mr. Schell is intended to state briefly the conditions which should govern the safety clearance by the Government of coloring agents, referred to as "organic chemical colors" for use in foods, drugs, and cos-

metics. While we are in complete sympathy with Mr. Schell's desire to have a brief bill, we must point out that in striving for brevity he has proposed language that is grossly deficient in that it fails to give either the Government or regulated industry adequate guidelines. To mention a few of the deficiencies, the bill provides no guides to the Secretary in those cases where he must allocate the use of a color as between competing industries because safety factors will not permit approval of all uses requested; the bill is deficient in that it does not provide any guidelines to the Secretary as to what would be regarded as "appropriate scientific procedures"; it omits a number of the safeguards which we regard as essential; and it makes no provision for the transitional period immediately after enactment when colors presently allowed in food, drugs, and cosmetics would go over to the new system.

We must recommend that the alternate bill suggested by Mr. Schell not be considered. We have, therefore, refrained from making detailed comment on it.

VI. MISCELLANEOUS

1. Mr. Arthur T. Schramm, speaking for the certified color industry on January 27, referred to the animal feeding studies which the Food and Drug Administration has conducted on a number of certifiable coal-tar colors as follows: " * * * new animal feeding studies had been conducted using quantities of colors far in excess of, and admittedly unrelated to, amounts ingested by human beings."

The Department of Health, Education, and Welfare does not agree that the colors were fed to test animals at unrealistic levels, as the witness implied. On the contrary, the levels of feeding were chosen to permit the Department to judge the harmlessness of the colors for uses that would involve ingestion.

In the color case that was decided by the Supreme Court on December 15, 1958 (*Flemming v. Florida Citrus Exchange*) the Court upheld the Department's view. It stated in part: "The color substance appeared to have been administered at toxicologically significant levels."

2. Dr. Thomas Carney indicated that the safety of diethylstilbestrol in man and animal has been fully established. The Department finds it necessary to challenge this. At a matter of fact, diethylstilbestrol is a very potent drug which, as Dr. Harold Aaron testified later, should be prescribed by physicians with care. Incidentally, there is a major error in some of the calculations made by Dr. Carney. On page 449 of the transcript of the hearing he indicates that an amount in some diabetic women (120 milligrams per day) would be more than a billion times the amount of hormone that would be present in one pound of meat assumed to contain a residue of 0.3 parts per billion. A check of the calculations indicates that Dr. Carney's figure is in error by more than a thousandfold.

3. Dr. Carney also indicated (p. 455 of the transcript) that a number of common items of food have been implicated in carcinogenicity in animals. He does not say, and our scientists do not know, that these foods have been shown to produce cancer when fed. In the absence of a showing that they produce cancer by feeding, it would appear that the listing of the many foods has questionable value in this proceeding.

4. Mr. John Worley indicated (p. 432 of the transcript) his understanding that cancer can be produced when you feed rats sugar or salt making up 2 to 5 percent of their diet. We do not know of any experiments showing this result.

5. Dr. Kenneth Mulford (p. 391 of the transcript) refers to an article in the scientific literature which appears to show that the feeding of hard boiled eggs to mice produces cancer. Our experts, who are ac-

quainted not only with this article but with the general research going on in the cancer field, advise us that the experiment to which Mr. Mulford refers does not prove that eggs contain a carcinogenic chemical. The experiment does not adequately deal with a number of important questions that would have to be resolved to permit the conclusions the witness implied.

6. In his letter of February 4, 1960 to the committee, Mr. Scheil reports a statement, attributed to an officer of a Canadian fruit importing association, "that Canada's 1956 embargo on color added oranges was solicited and induced by U.S. Food and Drug Administration." This statement is false.

7. A number of other statements in Mr. Scheil's letter of February 4, 1960 are false or distort the true facts significantly. Since they do not bear directly upon the suitability of the bills now being considered by your committee we will not burden the record with a detailed refutation. We would not, however, wish to indicate by silence that we concur in them.

ENCLOSURE II

CHANGES IN TRANSITIONAL PROVISIONS (TITLE II) OF S. 2197 TO PROVIDE FOR OPPORTUNITY FOR HEARING AND JUDICIAL REVIEW IN CERTAIN CASES

1. On page 19, line 24, strike out "Regulations" and insert "Except as provided in subparagraph (C) of this paragraph, regulations".

2. On page 20, line 8, strike out "(B)" and insert "(D)".

3. On page 20, between lines 7 and 8, insert the following new subparagraphs (B) and (C):

"(B) If the Secretary, by regulation—

"(1) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1) (E) of this subsection; or

"(1) has, pursuant to paragraph (1) (C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

"(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less

restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review."

ENCLOSURE III

CHANGES IN HEARING PROVISION OF TITLE I OF S. 2197 AND OF H.R. 7624 TO INSERT TIME LIMITS GOVERNING NOTICE OF A PROPOSAL AND THE SECRETARY'S ACTION ON A PETITION

Redesignate indented clauses (1) and (2) of section 706(d) (p. 13, lines 13-20, of S. 2197; p. 13, lines 10-17, of H.R. 7624) as clauses (2) and (3); and insert the following new indented clause (1):

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than 180 days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;"

ENCLOSURE IV

CHANGES IN TRANSITIONAL PROVISIONS (TITLE II) OF S. 2197 AND OF H.R. 7624 RELATING TO THE CONTINUED AVAILABILITY OF COLOR CERTIFICATION FEES AND THE CONTINUED EFFECTIVENESS OF REGULATIONS GOVERNING PAYMENT OF SUCH FEES

Add, at the end of section 203(d) (2) (A) of the bills, the following sentence:

"Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act; shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended."

Mrs. SULLIVAN. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Missouri, who testified before the committee and who has contributed a great deal to this subject.

Mrs. SULLIVAN. Mr. Speaker, let us not pretend that this is a bill to strengthen the Federal Government's protections for the consumer in the use of artificial coloring in or on food, drugs, and cosmetics. I will concede that the bill, as reported by the Committee on Interstate and Foreign Commerce after many months of careful and conscientious consideration, is a much better bill than the one which galloped through the Senate last year without debate and even without hearings. The House bill does less damage to the consumer than the bill passed by the Senate. It is not as dangerous. But as far as I can see, it does not do anything affirmative for the

consumer and is based almost entirely on economic rather than health considerations.

When I testified before the committee during hearings on this legislation last January, I pleaded for caution on this bill—and I am glad that the committee did go slowly and with great care, calling in a group of outstanding scientists for panel discussions on the problem. For that, I am grateful. For the further fact that the committee refused to delete the Delaney anticancer clause from the bill—the same clause which we wrote into the Food Additives Act of 1958—I am doubly grateful. The Senate bill did not include the Delaney anticancer clause. It is in that respect that this bill is far superior to the Senate bill.

But in addition to pleading for care and caution in the consideration of this legislation, I also asked the committee during my appearance in January to broaden the scope of their study to include not only the color additives problem, but also the question of additives in cosmetics—a serious area of health danger—an area now covered by completely obsolete law—and I also urged that any legislation reported by the committee on color additives also close the loopholes which have been discovered in the Food Additives Act and the Pesticides Act and in the basic Food and Drug Act of 1938.

Unfortunately, the bill which the committee has reported is restricted only to this narrow question of coal-tar colors and is based almost entirely, as I said, on a desire to bail out the lipstick makers and the margarine makers and the other industries which use not-quite-harmless coloring matter for the sole purpose of making their products look more attractive to the buyer.

For instance, the Secretary of Health, Education, and Welfare made a strong request to the committee for an amendment on this bill to cover a serious loophole in the Food Additives Act of 1958. The Secretary explained how that loophole got into the act—because the Department apparently made a too-sweeping statement in some of the language which it drafted for the Food Additives Act several years ago. As a result, any food additive which was ever cleared by any Government agency as being safe for the use intended, now has what amounts to an unjustified "grandfather's clause" protecting it from removal action unless the Government has proof of its danger. This is an intolerable interpretation of what Congress intended. The committee, however, has failed to recommend the repeal or modification of this language in the 1958 act, even though this provision has been causing great difficulty and, in the case of the stilbestrol-treated chickens, could be handled only through voluntary agreement at a cost of many millions of dollars to the Federal Treasury and the taxpayers.

The committee states in its report on H.R. 7624 that it is not recommending amendment of the Food Additives Act of 1958 in the color legislation because it did not consider such amendments directly germane to the color bill. It said

it would consider such amendments at a later date—presumably in the next Congress. I think this is a much more serious problem, however, than the coal tar color problem.

Mr. Speaker, for a variety of reasons, I do not find it possible to support this bill. The confusion it seeks to clear up stems from the use by food and cosmetics firms of colors which are not completely harmless. The producers and users of these chemical dyes are understandably anxious to get the go-ahead for continued use of these colors even though the colors can no longer meet the safety requirements of the law. The present law has been described as too rigid. This may be true. It is 22 years since the law on colors was enacted in 1938 and it may be too strict now. But it is rigid on the side of the consumer.

However, as I told the committee, Mr. Speaker, rather than rush into law a special interest bill to bail out the cosmetics and margarine and bakery and frozen food and ice cream and other industries which use artificial coloring strictly for product eye appeal, let us tighten up the weak points and provisions in the law while we clarify the overly rigid ones. Let us overhaul the whole structure of food, drug and cosmetics legislation intended to protect the consumer. The loopholes are wide—gaping—in these laws—even today.

I cannot support a bill which weakens our consumer protections for the economic benefit of manufacturers using coloring material which is not completely safe. I particularly cannot support such weakening of our consumer laws, when we are not taking any steps at the same time to close glaring loopholes in the Food, Drug and Cosmetics Act.

In my testimony before the committee, I covered these loopholes in some detail, in relation to this legislation to help the manufacturers using artificial colors, and I include that detailed testimony now, as follows:

THE NEED IS TO STRENGTHEN, NOT WEAKEN, THE FOOD, DRUG AND COSMETIC ACT

(Testimony of Congresswoman LEONOR K. SULLIVAN, of Missouri, before House Committee on Interstate and Foreign Commerce on proposed color additives legislation, January 27, 1960)

The tremendous turnout you had here yesterday morning when Secretary of Health, Education, and Welfare Arthur S. Flemming testified on the color additives issue indicated clearly the widespread interest in the subject matter of these hearings. I doubt if you ever tried to squeeze more spectators into your hearing room. Obviously, this legislation is serious to many groups in our society—to the food and chemical and cosmetics industries, and to the general public—particularly the housewife.

My purpose in appearing before you this morning is to urge you to please take your time on this legislation. I am not going to suggest that you sit on the bills and do nothing about them, but I sincerely urge that you make haste slowly—that you study this matter as carefully as any issue ever to come before the committee, for you are dealing with the health of the American people in the most direct manner possible.

CIRCUMSTANCES OF SENATE ACTION

I make such a point of urging caution because I know you are under strong pressures to act quickly on color additives legislation.

We all know that late in the session last year, without any hearings at all and under procedures which seemed to indicate it was a very minor and routine bill, the Senate, by unanimous voice vote, passed a most far-reaching bill on color additives. We know it is a defective bill in a most serious respect. Yet it came out of committee, as I said, without hearings, and was called up under a routine call of the calendar for passing by unanimous consent, with no full explanation and with virtually no debate or even discussion. The only thing we find in the CONGRESSIONAL RECORD of the debate which occurred was a colloquy over the effects of S. 2197 on the right of Florida citrusgrowers to use a not-quite-harmless coal tar color in coloring Florida oranges. When the Senator from Florida was assured that S. 2197 would not interfere with the use of citrus red No. 2 on Florida oranges, the bill passed automatically.

Some of the members of the committee will recall that immediately after the Senate acted on this matter last August, I contacted them to urge that there be no such precipitate action in the House. I appreciate the fact that no attempt was made to jam through a bill in the frantic closing hours of the last session. I appreciate the fact that full hearings are now scheduled into the color additives issue.

DELANEY ANTICANCER CLAUSE A MINIMUM REQUIREMENT

I don't want my testimony to imply anything improper on the part of anyone in the Senate—I just think that in the closing rush of last August this bill could not possibly have received the close attention it deserved. Nevertheless, the circumstances of the Senate's action were such that I find it very hard to feel right about this legislation, even if we close up its most glaring loophole by inserting the same kind of anticancer provision which Congressman DELANEY wrote into the Food Additives bill in 1958. I cannot understand why the bill as it came from the Senate did not include such a clause. Without it, I think this legislation would be far worse than present law covering the use of coal tar colors. Furthermore, by taking out from under the Food Additives Act of 1958 dyes made from other than coal tar bases, it would increase the danger of carcinogens in our diets, unless, of course, the provisions of the Delaney amendment are written into this bill as a minimum requirement.

Obviously, then, despite its impressive title as a bill to "protect the public health," S. 2197 as it passed the Senate would weaken the protections of the Food, Drug, and Cosmetics Act. And this is certainly no time in our history to be weakening the consumer protections of our laws. On the contrary, our laws to protect the consumer need strengthening, and this is particularly true of the Food, Drug, and Cosmetics Act. We have put a number of patches on it in recent years, but it is far from being as strong as it should be.

HOW WOULD CONSUMERS BENEFIT?

Clearly, some of the shortcomings of the present act do exist in this area of coal tar colors. But I am not convinced the deficiencies are as serious to the consumer as they seem to be to many of the industries affected.

The present law says in effect that no coal tar color can be used in or on food or cosmetic unless it is deemed harmless. This law grew out of the conviction of scientists that coal tar colors are inherently risky and should be circumscribed in use to such an extent that if there is any question at all about their safety they should not be used in or on food, or in other substances which may be ingested. In recent years, new testing methods have shown that some of the coal tar colors previously thought to be

harmless are not in fact completely harmless although they may be, and probably are, safe in the manner normally used in commercial products. Nevertheless, because these colors cannot pass the test any longer of being harmless under all circumstances, the law states they cannot be used—they must be withdrawn. As a result some of the yellows used in coloring margarine and butter, some of the reds—most of the reds, I believe—in lipsticks, and various other familiar colors used in foodstuffs are in the process of being delisted—of being prohibited for use on products which people eat (or, in the case of lipsticks, swallow).

Mr. Chairman, I am not quite sure I see how the consumer is being damaged by the removal of these colors. Nor do I see why the consumer would benefit from the changes suggested in this legislation. I can readily see why many industries want legislation enacted which would set up entirely new criteria for approving the use of coloring matter, including the setting of tolerances for the use in or on food of apparently harmless quantities of dyes which may not be harmless in greater quantities. But I do not yet see how the consumer interest would benefit from this color additives legislation.

CAN WE BE CERTAIN THAT "SAFE" LEVELS ARE REALLY SAFE?

True, the proposed legislation would place on the manufacturer, not the Government, the burden of proof for establishing the safe levels of coal tar colors. But as our whole experience with the coal tar colors shows, today's proof of safety may be inadequate in terms of tomorrow's testing methods. Do we then go to the consumer and say, "Sorry, we made a slight mistake; a coal tar color we knew was not completely harmless but which we thought was safe to use in certain concentrations has now turned out to be unsafe and dangerous, and if you've been eating it in your food we're very sorry about it?"

Mr. Chairman, just how important is it to have these artificial colors in foodstuffs if there is any danger whatsoever to the consumer through their use? True, the margarine manufacturers want their product to look like butter; the butter producers want their butter to look like yellow butter regardless of its natural color; the Florida citrusgrowers want their greenish-looking oranges to be orange in color, and the manufacturers of all sorts of products—sausage casings, cakes, cookies, pies, bread, processed cheese, spreads, canned and frozen vegetables, confectionery, ice cream, gelatin desserts, puddings, and so on—all want to dazzle us with the looks of their products even if they have to create the look artificially with coal tar colors which cannot any longer pass the test of being harmless.

Now we are told that the consumer wants and demands these attractively colored foods and therefore it is an economic necessity for industry to provide them.

CONSUMERS ASSUME DYES ARE SAFE

I do not doubt that a housewife buying oranges will generally select the product which looks more natural by reason of having been dyed to look that way rather than the greenish one next to it which appears to be unripe; I do not doubt that in selecting a lipstick she will want the color which, to her, best matches her complexion and outfit; I do not argue that in buying processed foods, she is attracted by the appearance of the product.

But the point is that the consumer, in buying these brightly colored or natural-looking colored items in the store, believes—takes it for granted—that the coloring dyes used are safe, and that otherwise their use would not be permitted by the Federal Government.

What this proposed legislation would do is to say the coloring matter frequently used

may not be entirely safe under all circumstances but we believe and trust and hope and have reason to think it is safe in the amount used and in the manner used. And so the housewife will then continue to be able to buy margarine which looks like butter, and butter which, because of a deeper yellow shade, looks more like butter, and so on, even if the looks are artificially contrived through use of not-quite-harmless dyes.

Under S. 2197 as it passed the Senate, these dyes could even be cancer inducing, yet could be used if the manufacturer could establish that the cancer manifested itself only at substantially higher levels of concentration.

CANCER-INDUCTION IS CUMULATIVE PROCESS

This, of course, does not jibe with the findings of outstanding cancer experts that cancer induction is a cumulative process which begins with the first dose of the cancer-inducing agent. Secretary Flemming referred to this matter at some length in his prepared testimony yesterday and in a technical report he also submitted, so I need not go into it in any detail. Many of you—perhaps all of you—saw the letter I obtained on this matter last year from Dr. Harold F. Blum of the National Cancer Institute and which I placed in the CONGRESSIONAL RECORD of August 27 at pages A7482-A7483 in direct reference to the bill which had just passed the Senate and which is now before you. But in view of Secretary Flemming's technical report from the NIH, I think we can now take for granted the fact that carcinogens must not be allowed in food or in anything ingested. Present law already prohibits this as far as all food colors are concerned—the coal tar colors under the basic Food and Drug Act of 1938 and the other colors under the Food Additives Act of 1958.

So, again, I ask, How does this legislation help the food consumer?

We are told that the job of analyzing and retesting all of the coal tar color already in use or authorized for use to see if they are still harmless would take the Food and Drug Administration at present levels of operations at least 20 years. This legislation would throw that burden onto the manufacturers and they would have to complete the task in 2½ years. Frankly, I think what would happen is that at the end of 2½ years we would either be flooded with anguished demands for an extension of time, or many of the dyes would then go off the market because the cost of proving their safety was too high. I, for one, would be willing to give the Food and Drug Administration the funds to do this testing itself—under the present law.

BROADEN SCOPE OF HEARINGS

I realize, Mr. Chairman, that I am not helping the committee very much if all I do in testifying here is to say "take it easy." I know you have a problem to contend with and many pressures upon the committee to act quickly. Therefore, I think it would be constructive to make this suggestion:

Broaden your hearings and your studies to include not just this one question of coal tar colors and other color additives but to include all of the aspects of the Food, Drug, and Cosmetics Act. It is time for that kind of look at the overall picture. In the past 6 months or so we have had one explosion after another over phases of the law and its operation—cranberries, stilbestrol in chickens, the lipstick crisis, the food additive clearances, and so on. I think tremendous progress has been made in alerting the general public to some of the issues involved in Food, Drug, and Cosmetics legislation, and that this is an excellent time to take a good hard look at the basic law and its patchwork amendments and to undertake a tightening

of many of their provisions. This would, of course, carry some dangers with it—the danger perhaps, that groups which have suffered economically from operation of some of the consumer protections of the law would attempt to use such hearings and any new legislation as a means for weakening rather than strengthening the law. But I don't think they could succeed—certainly not if all of us who are deeply concerned about this problem are willing to fight off the pressures to weaken the law.

And the end result could well be a general strengthening of the law—so that the Government, for instance, would no longer have to rely on voluntary agreement in the poultry industry to take stilbestrol out of poultry feed; so that, for instance, cosmetics which are now in the twilight-zone of governmental protection can be put under the same stringent tests for safety as our food additives must now pass; so that other loopholes in the law may also be closed.

WE NEED PRETESTING OF COSMETICS

I think color additives legislation in the context of that kind of approach would be far better legislation than either of the bills now before you. For such an omnibus approach would permit you to eliminate the loopholes in the 1938 law under the "new drug" sanction and the similar loophole in the 1958 amendments which requires FDA to prove the harmfulness of any additive which had previously been sanctioned for use by a governmental agency. Secretary Flemming in his testimony referred to the stilbestrol problem and the unfairness, as well as the danger to the public, of these so-called "grandfather's clauses" covering chemicals once approved and thereafter protected against delisting until the Government can definitely prove their harmfulness.

In the field of cosmetics, the law is hopelessly obsolete. The Government at present cannot move against a suspect cosmetics item until it has proof of the product's harmfulness. My bill, H.R. 1360, and a similar bill by Congressman DELANEY, would provide the same consumer safeguards on ingredients in cosmetics that the food additives amendments of 1958 provided in connection with the use of chemicals in food. These cosmetics bills have been pending before you for some years, without any action or even hearings. I think this is the year and this is the time—in connection with the color additives bills—to take up this closely related subject of safe cosmetics.

The color additives bill makes it imperative that we do so. For the color additives bill would not only change the basic under which coal tar colors could be used in cosmetics. It would also establish, for the first time, a basis for clearing in advance the safety of non-coal-tar colors used in cosmetics. That would be helpful. But what of all of the other ingredients in cosmetics? If we are going to require manufacturers to prove the safety of their non-coal-tar color additives in cosmetics, why not in the same legislation and at the same time and under the same standards require the manufacturer to establish the safety of all ingredients in his cosmetics product?

At present, as you know, enough women must be harmed by a new cosmetic item to alert the Food and Drug Administration into looking into the matter; then the FDA must prove the product harmful in order to remove it from the market. I receive letters from women from all over the country complaining about various cosmetics they have used—shampoos or wave set products they claim have caused them to lose their hair, polishes which set up allergic reactions, lotions and creams and powders and lipsticks and deodorants and what not which caused embarrassment, discomfort, or pain. I usually pass these complaints along to FDA and

sometimes they find the product involved warrants a fullscale investigation and other times they will report merely that the reaction was probably a rare allergic one.

WOMEN WANT SAFE LIPSTICKS

But if a woman is allergic, the label on a cosmetics item tells her nothing. She has to learn the hard—and painful—way.

Speaking as a woman as well as in my capacity as a Member of Congress, I urge you, Mr. Chairman, to go slow on this color additives bill and to enlarge the scope of your hearings to include all issues involved at present in the Food, Drug, and Cosmetics Act. As a woman, I am aware of the fact that some of our favorite lipstick shades may soon be off the market unless this color additives bill is passed quickly. But I am not convinced we would be doing the women of this country any favor at all to assure them the continued availability of lipstick shades which are not safe to use. True, it is claimed we don't swallow our lipstick. But I think the people who make that claim don't use the "stuff" themselves.

We like the bright and light shades but if they cannot safely be produced, then we prefer to do without these particular shades. In any event, I am sure the cosmetics industry is resourceful enough—it is an extremely resourceful industry—often too much so—but I am sure it is resourceful enough to find substitute colors if it has to. And I think every woman would agree that rather than use unsafe coloring matter, we would be quite happy to settle for a darker shade if necessary, just so long as we could be completely assured it was safe.

I don't think, under this proposed legislation, that any such flat and unequivocal guarantee of safety could be made about any coal-tar color for which a tolerance had to be set. I will not and can not argue with the scientists on that, but it is my personal opinion—if a coal tar color is unsafe in any quantity, no matter how large, my feeling is it should not be used at all in foods, drugs, or cosmetics.

If, on the other hand, legislation is absolutely necessary to clear up some of the confusion in the color additives field, then I urge that it be done only as part of an omnibus bill closing all loopholes in present law and including comprehensive, safe cosmetics legislation.

Mr. ALLEN. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Illinois.

Mr. ALLEN. I want to thank the gentleman for the fine explanation he has made of this bill and what he said in regard to certain changes that you contemplate making or, at least, will attempt to make in conference. I am in sympathy with the overall purposes of the bill, and I favor its passage.

Mr. ROGERS of Florida. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Florida, who also has contributed a great deal to this program.

Mr. ROGERS of Florida. Mr. Speaker, the color additive amendments of 1960 as contained in H.R. 7624 are designed to replace the inconsistent and in some instances, outmoded, provisions which govern the use of different kinds of color for articles covered by the Federal Food, Drug, and Cosmetic Act, with a scientifically approved, uniform system for the listing of color additives which may safely be used in food, drugs, and cosmetics.

As a good portion of this proposal is of necessity couched in technical terms,

I would like to explain briefly some of its provisions as I understand them.

Under existing law, with one exception, the Secretary of Health, Education, and Welfare is without the authority to admit a coal tar color to listing under tolerance limitation. It must be harmless per se in order for the Secretary to admit it to listing.

A coloring material not classified as a coal tar color is not subject to any pretesting, listing or certification requirements in the case of cosmetics or drugs except as pretesting may be required as an incident of official clearance of a new drug.

The provisions of this bill would incorporate the safe-for-intended-use principle with respect to all color additives except those found to induce cancer in man or animal. In the case of cancer-producing additives, the Secretary is not permitted to set tolerance levels. The bill would make the pretesting and certification requirements of existing law applicable to all colors whether they be coal tar derivatives or otherwise.

The bill provides a 2½-year transitional period during which time users of color additives would be required to demonstrate to the satisfaction of the Secretary that these colors were safe for the use for which they are intended. Also, during this transitional period, those colors which have been commercially established are permitted continued use pending completion of tests to determine whether they may be listed permanently. The burden of proving the safety of each additive is on the petitioner and if the additive is shown to be safe, it is entitled to permanent listing under the provision of the Federal Food, Drug, and Cosmetic Act. A determination by the Secretary in this respect is subject to judicial review.

Once a color additive is entitled to listing under permanent provision of the law and is, in fact, listed any decision to delist that additive except in emergencies, places on the Secretary the burden of establishing doubt of the additive's safety. Where the Secretary finds doubt as to the safety of a color on the permanent list, he issues, to interested parties, an inactive order to that effect.

Within a 30-day period, any person adversely affected by the proposed order may petition for a hearing. If the Secretary sustains the burden of proof and establishes the doubtful safety of the additive, a delisting or active order is entered. Here again, judicial review of the Secretary's determination is assured.

Under the bill a special procedure is set up to handle those situations where a proposed delisting or a refusal by the Secretary to list a color involves the possibility that such color may be cancer producing.

The so-called Delaney amendment provides that a color additive shall be deemed unsafe and shall not be listed if it is found by the Secretary to induce cancer in man or animal. The "safe for use" principle does not apply to situations where carcinogenicity is at issue.

Under this bill, the petitioner for the listing of a color suspected of being a

carcinogen or the Secretary may request that the matter be referred to an ad hoc advisory committee composed of qualified scientific experts. These experts would be selected by the National Academy of Sciences to study the evidence presented and make recommendations to the Secretary. I would like to emphasize that the provision relating to the ad hoc advisory committee does not in any sense modify the effect of the Delaney anticancer clause. Cancer producing substances are unequivocally barred as in the food additives amendment. My purpose in recommending that the committee add this provision to the bill was to give added assurance to the petitioner for a color listing that his application would be reviewed by an impartial board of experts specifically instituted to study the evidence presented. My amendment is similar to that found in the pesticide amendment and takes into account the fact that men of science might have divergent views on the same question. It provides the petitioner with the assurance that his petition will receive the most detailed consideration thus avoiding any presumption of arbitrary action.

If the additive is, in fact, found to induce cancer, its use is banned by active order. The rights of the petitioner are further safeguarded by affording him judicial review based on a fair evaluation of the entire record of the proceedings.

The fact that the Department of Agriculture and the President's special panel on color additives recommended that consideration be given to the exercise of scientific judgment in situations involving the question of carcinogenicity, imposes, in my opinion, an affirmative duty on the Congress and the appropriate executive agencies to conduct a continuing review of the effect of the Delaney clause on users and consumers. This is especially true when we consider that during the course of the testimony on this bill, the point was made by scientific experts that many substances when administered to laboratory animals in certain quantities and under certain conditions are capable of inducing cancer.

There are a couple of additional points involving other parts of the bill, I would also like to touch upon. These points are covered very well in the report, and my purpose in mentioning them is solely to add to their legislative history by setting forth the intent of the committee.

Pesticides used on raw agricultural commodities whose purpose is not to impart color are specifically exempted from the provisions of this bill.

The ethylene process, which is used in the coloring process on mature citrus fruit does not impart color but rather serves to speed up the natural coloring process. The report specifically states that this process is without the purview of this bill.

The Secretary of Health, Education, and Welfare, by letter to the committee, which letter is contained in the report, declares that the use of artificial coloring on mature citrus fruit does not promote "deception" as that term is used in the bill.

With these understandings, Mr. Speaker, and because the bill before us is the result of exhaustive hearings and study and is, in my opinion, a bill in the best interests of consumers and manufacturers alike, I respectfully urge its enactment.

(Mrs. SULLIVAN, Mr. ROGERS of Florida, and Mr. ROBERTS asked and were given permission to revise and extend their remarks.)

Mr. ROBERTS. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Alabama, also a great contributor to this legislation.

Mr. ROBERTS. Mr. Speaker, this legislation is very important to the public and many industries. As the distinguished chairman of the committee, the gentleman from Arkansas [Mr. HARRIS] has explained, the public will be protected by the requirement that the Secretary of Health, Education, and Welfare will have to approve each and every color for use in food, drugs, and cosmetics. This means that each and every color will have to be tested and found to be safe and suitable for use. No color will be permitted if it is found, on the basis of scientific evidence, to produce cancer in man or animal.

The bill will help industry, particularly the cosmetic industry, by permitting the continued use of certain coal-tar colors under safe tolerances to be determined by the Secretary. As the gentleman from Arkansas has stated, a number of coal-tar colors have already been banned, and others are threatened with being banned if this legislation is not enacted this year. Many of these colors will be perfectly safe for use under tolerance limitations. The Secretary does not have authority under present law to set such tolerances. This bill will give him the authority he seeks.

I join with my colleagues in urging the House to pass this bill.

Mrs. CHURCH. Mr. Speaker, will the gentleman yield?

Mr. HARRIS. I yield to the gentleman from Illinois.

Mrs. CHURCH. I would like to express to the gentleman and also the gentleman from New York [Mr. DELANEY] the interest which I personally feel in the object of this legislation. I am sure they are both aware of it. I would like to say to the chairman that I have had one major question asked me and that is whether or not the bill provides sufficient safeguards against arbitrary decisions of any Secretary of Health, Education, and Welfare.

Mr. HARRIS. Yes; we do provide for adequate safeguards against arbitrary action by the Secretary.

Mrs. CHURCH. Is there any appeal from the decision of the Secretary?

Mr. HARRIS. Any petitioner who may be adversely affected by a proposed action by the Secretary may petition the Secretary for a review of the proposed order and request a public hearing, and so forth. With respect to the question whether a substance is carcinogenic, the bill provides for the appointment of an Ad Hoc Scientific Advisory Committee of experts to advise the Secretary.

Mrs. CHURCH. I would not want the gentleman to feel that my question indicated any lack of interest on my part. May I express regret that we were not able to hear the statement of the gentlewoman from Missouri, who has done so much on this subject.

Mr. SCHENCK. Mr. Speaker, I move to strike out the last words.

Mr. Speaker, I do this only for the purpose of expressing very sincere commendation to the gentleman from New York [Mr. DELANEY] for all the work he has done on this subject, to the chairman of our committee, and the members of our committee, who have devoted so many hours to hearings on this important subject. I feel that this legislation has had unusually thorough hearings; that all necessary safeguards have been built into the legislation; that it is worthy of your support, and that the entire subject is of tremendous importance to our entire Nation. The Secretary of Health, Education, and Welfare, the Food and Drug Administration, and all the other scientists have given great assistance and expert testimony before our committee.

Mr. KYL. Mr. Speaker, will the gentleman yield?

Mr. SCHENCK. I yield to the gentleman from Iowa.

(Mr. KYL asked and was given permission to extend his remarks at this point in the RECORD.)

Mr. KYL. Mr. Speaker, the gentleman from Iowa is certainly in accord with the general provisions of the measure before the House. However, he has reservations in regard to the Delaney clause because of the difficulty of exercising proper judgment in administration even with the ad hoc Advisory Committee.

In the first place it seems rather foolish to limit emphasis in this bill to one aspect—cancer. Admittedly, safety with regard to cancer is extremely difficult to define in simple terms. Here we are prohibiting use of a substance. The prohibition is based on the assumption that a substance which increases the incidence of cancer when included in the diet of animals at any dose may increase the incidence of cancer in man. Measurements are most difficult. Many chemicals may be hazardous in large quantities and under conditions of unusually long exposure, but harmless under all normal circumstances.

It is certainly hoped that if the Delaney amendment is adopted the regulatory agencies will apply the rule of reason in their administration.

Mrs. ROGERS of Massachusetts. Mr. Speaker, will the gentleman yield?

Mr. SCHENCK. I yield to the gentleman from Massachusetts?

Mrs. ROGERS of Massachusetts. Mr. Speaker, I am delighted that this bill will soon be passed. Some years ago the House passed a bill on the Consent Calendar. I took it over to the other body in the afternoon and the distinguished late Senator George got it through the Senate in a few hours' time and it was signed by the President and became law in record time.

I commend the gentleman from New York [Mr. DELANEY] for his tireless work

on matters pertaining to the dread disease of cancer—and all the others who have helped.

It is very suitable this bill should come up at this time and I commend those who are bringing it here. I am heartily in favor of it.

Mr. SCHENCK. Mr. Speaker, I yield back the balance of my time.

The SPEAKER pro tempore. The question is on engrossment and third reading of the bill.

The bill was ordered to be engrossed and read a third time, was read the third time and passed.

The SPEAKER pro tempore. The question is on passage of the bill.

The bill was passed.

A motion to reconsider was laid on the table.

Mr. HARRIS. Mr. Speaker, I ask unanimous consent for the immediate consideration of the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions—including maximum tolerances—under which such additives may be safely used.

The Clerk read the title of the bill.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Arkansas?

There was no objection.

The Clerk read the bill, as follows:

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this act may be cited as the "Color Additive Amendments of 1959."

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Definitions

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or".

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays."

Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

(2) Section 402(c), as amended, of such act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(3) Section 403 of such act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(1) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

(b) (1) Clause (4) of section 501(a) of such act (relating to drugs deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows: "(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

(2) Section 502 of such act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

(c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706 (a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

"(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

Regulations to assure safety of color additives for foods, drugs, and cosmetics

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "Sec. 406." in such section;

(2) repealing section 504;

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or (b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604"; and (C) inserting the word "or" after "501(b)."

(b) Section 706 of such Act is amended to read as follows:

"Listing and certification of color additives for foods, drugs, and cosmetics"

"When Color Additives Deemed Unsafe"

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a)(4), or section 601(e), as the case may be, unless—

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

"Listing of Colors"

"(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or

articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(A) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(B) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(C) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(D) the availability of any needed practicable methods of analysis for determining the identity and quantity of (i) the pure dye and all intermediates and other impurities contained in such color additive, (ii) such additive in or on any article of food, drug, or cosmetic, and (iii) any substance formed in or on such article because of the use of such additive.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as

affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors"

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided,* That with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations"

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsections (b), (c), or (e) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) the Secretary's order after public hearing (action upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f) (2); and

"(2) the scope of judicial review of such order shall be in accordance with the third sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

"Fees"

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions"

"(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

"Confidentiality of trade secrets"

SEC. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

Changes in cross-references and terminology

SEC. 105. Such Act is further amended by—
(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), "404, 406(b), 504, 506, 507, or 604", and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufac-

turer's guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to non-nutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Definitions

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

Effective date

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

Provisional listings of commercially established colors

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had

been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either (A) on the day preceding the enactment date was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) Regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706.

(B) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the pur-

pose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraph (1) (A) and (C) with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1) (A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such uses or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

Effect on Meat Inspection and Poultry Products Inspection Acts

SEC. 204. Nothing in this Act shall be construed to exempt any meat or meat food product or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).

Mr. HARRIS. Mr. Speaker, I offer an amendment.

The Clerk read as follows:

Amendment offered by Mr. HARRIS: Strike out all after the enacting clause of S. 2197 and insert the provisions of H.R. 7624 as passed, as follows: "That this Act may be cited as the 'Color Additive Amendments of 1960.'"

"TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

"Definitions

"SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

"(a) Paragraph (s) of such section (defining the term 'food additive') is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or"

"(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

"(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

“(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

“(2) The term “color” includes black, white, and intermediate grays.

“(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest.”

“Colors or colored articles—when deemed to be adulterated or misbranded foods, drugs, or cosmetics

“Food

“SEC. 102. (a) (1) Clause (2) (A) of section 402(a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: ‘other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive.’

“(2) Section 402(c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

“(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).’

“(3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

“(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.’

“Drugs

“(b) (1) Clause (4) of section 501(a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal tar color) is amended to read as follows: ‘(4) If (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).’

“(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

“(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.’

“Cosmetics

“(c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

“(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).’

“(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

“(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).’

“Regulations to assure safety of color additives for foods, drugs, and cosmetics

“SEC. 103. (a) Such Act is further amended by—

“(1) repealing subsection (b) of section 406 and striking out the subsection designation ‘(a)’ after ‘SEC. 406.’ in such section;

“(2) repealing section 504;

“(3) repealing section 604; and

“(4) amending section 701(e) by (A) striking out ‘406 (a) or (b)’ and inserting in lieu thereof ‘406’; (B) striking out ‘504, or 604.’; and (C) inserting the word ‘or’ after ‘501(b).’

“(b) Section 706 of such Act is amended to read as follows:

“Listing and certification of color additives for foods, drugs, and cosmetics

“‘When Color Additives Deemed Unsafe

“SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a) (4), or section 601(e), as the case may be, unless—

“(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

“(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

“Listing of Colors

“(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

“(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable

and may safely be employed for such general use.

“(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

“(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereinafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

“(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulation, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term “food additive” because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

“(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

“(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive,

“(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substance_s in such diet;

“(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

“(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

“(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or

animal to such additive, it is found by the Secretary to induce cancer in man or animal.

“(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

“(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

“(iii) Where—

“(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

“(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

“(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee

and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

“(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

“(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

“(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

“(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

“(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

“‘Certification of Colors

“(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed

color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

“‘Procedure for Issuance, Amendment, or Repeal of Regulations

“(d) The provisions of section 701(e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b) (5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

“(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

“(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

“(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f) (2); and

“(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

“‘Fees

“(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

“‘Exemptions

“(f) The Secretary shall by regulation (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.

“‘Confidentiality of trade secrets

“Sec. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out ‘or 704’ and inserting in lieu thereof ‘704, or 706’.

"Changes in cross-references and terminology"

"Sec. 105. Such Act is further amended by—

"(a) striking out, in section 301(1) thereof (relating to forgery or unauthorized use of certain identification devices), '404, 406 (b), 504, 506, 507, or 604', and inserting in lieu thereof '404, 506, 507, or 706';

"(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word 'coal-tar' wherever it appears in such clause, and (2) inserting after the word 'color', wherever it appears in such clause, the word 'additive'; and

"(c) striking out 'harmless coloring' in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof 'authorized coloring'.

"TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS"

"Definitions"

"Sec. 201. As used in this title, the term 'basic Act' means the Federal Food, Drug, and Cosmetic Act; the term 'enactment date' means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

"Effective date"

"Sec. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

"Provisional listings of commercially established colors"

"Sec. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

"(2) For the purposes of this section, the term 'closing date' means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason

of a change in circumstances that basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

"(b) Subject to the other provisions of this section—

"(1) any color additive which, on the day preceding the enactment date, was listed, and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

"(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

"(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

"(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

"(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

"(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

"(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

"(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

"(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

"(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time,

be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

"(B) If the Secretary, by regulation—

"(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1) (E) of this subsection; or

"(ii) has, pursuant to paragraph (1) (C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

"(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

"(D) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in

effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

"(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1)(A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1)(A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1)(C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

"Effect on meat inspection and poultry products inspection acts"

"Sec. 204. Nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 U.S.C. 451 and the following)."

The amendment was agreed to.

The bill was ordered to be read a third time, was read the third time, and passed.

A motion to reconsider was laid on the table.

The proceedings whereby H.R. 7624 was vacated and that bill was laid on the table.

GENERAL LEAVE TO EXTEND

Mr. SCHENCK. Mr. Speaker, I ask unanimous consent that all Members may have 5 legislative days in which to extend their remarks on the color additives bill just passed.

The SPEAKER pro tempore. Without objection, it is so ordered.

There was no objection.

GORGAS MEMORIAL LABORATORY

Mr. DELANEY. Mr. Speaker, by direction of the Committee on Rules, I call up House Resolution 557 and ask for its immediate consideration.

The Clerk read as follows:

Resolved, That upon the adoption of this resolution it shall be in order to move that the House resolve itself into the Committee of the Whole House on the State of the Union for the consideration of the bill (H.R. 11123) to increase the authorization of appropriations for construction and equipment of fa-

cilities for the Gorgas Memorial Laboratory. After general debate, which shall be confined to the bill, and shall continue not to exceed one hour, to be equally divided and controlled by the chairman and ranking minority member of the Committee on Foreign Affairs, the bill shall be read for amendment under the five-minute rule. At the conclusion of the consideration of the bill for amendment, the Committee shall rise and report the bill to the House with such amendments as may have been adopted, and the previous question shall be considered as ordered on the bill and amendments thereto to final passage without intervening motion except one motion to recommit.

Mr. DELANEY. Mr. Speaker, I yield myself such time as I may consume, following which I yield 30 minutes to the gentleman from Illinois [Mr. ALLEN].

Mr. Speaker, House Resolution 557 provides for the consideration of H.R. 11123, a bill to increase the authorization of appropriations for construction and equipment of facilities for the Gorgas Memorial Laboratory. The resolution provides for an open rule with 1 hour of general debate.

H.R. 11123 would increase the amount authorized for the construction and equipment of facilities for the Gorgas Memorial Laboratory from \$250,000 to \$500,000. Such construction and equipment of facilities will include the preparation of plans and specifications, acquisition, alteration, expansion, and remodeling of buildings and site improvements, but excludes the cost of the acquisition of land, which is available without cost. This authorization request is not for a continuing annual appropriation.

The Gorgas Memorial Laboratory is in Panama City, Republic of Panama, and is the operating research establishment of the Gorgas Memorial Institute of Tropical and Preventive Medicine, Inc., located in Washington, D.C.

The Laboratory has been a leading center of research on tropical diseases and its contributions to new knowledge have been notable and of great benefit to all mankind.

Present plans envisage a three-story building providing up-to-date research facilities for present activities as well as for urgently needed new research in the fields of parasitology, epidemiology, pathology, serology, chemistry, physiology, virology, bacteriology, and botany. Space is also badly needed for visiting guest scientists and investigators most of whom come from the United States, and for cooperative departments to furnish supporting services such as glassware washing and culture media preparation, as well as quarters for small animals required for research. When the proposed new building is completed, all research projects, except those in zoology and entomology, would be housed in one structure, allowing not only for expansion, but also for greater efficiency through up-to-date facilities and better communication between the various groups of personnel.

The Laboratory's appropriate expansion because of research requirements should not be restricted in carrying out the humanitarian mission designed by its founders.

Mr. Speaker, I urge the adoption of House Resolution 557.

Mr. ALLEN. Mr. Speaker, I know of no opposition to the rule. I reserve the balance of my time.

Mr. DELANEY. Mr. Speaker, I move the previous question.

The previous question was ordered.

The SPEAKER pro tempore. The question is on the resolution.

The resolution was agreed to.

A motion to reconsider was laid on the table.

CORRECTION OF RECORD

Mr. MEADER. Mr. Speaker, on page 13213 of the Record of yesterday, in a colloquy between the gentleman from Texas [Mr. PATMAN] and myself, in the second column in the last statement I made in that colloquy the word "not" should be inserted before the word "be" so that the phrase would read, "he would not be against payment of these commissions." I ask unanimous consent that the permanent Record be corrected accordingly.

The SPEAKER pro tempore. Is there objection to the request of the gentleman from Michigan?

There was no objection.

WHAT DO MINNEAPOLIS PEOPLE THINK ON MAJOR ISSUES?

(Mr. JUDD asked and was given permission to address the House for 10 minutes and to revise and extend his remarks and include certain tables.)

Mr. JUDD. Mr. Speaker, I am reporting herewith a tabulation of the 10,368 replies to my annual questionnaire received from citizens in the Fifth Minnesota Congressional District.

My district consists of about two-thirds of the city of Minneapolis. I cannot ask the mail carriers to distribute the questionnaire to every mailbox, as can be done in rural areas, so I engage a mailing service to address a copy of the questionnaire to every name in the telephone book with an address in the district. Unavoidably, this means that residents without telephones are missed and also a few questionnaires are addressed to persons recently deceased.

To get replies from as many citizens as possible, I suggest that each person in a household use a different colored pencil or ink, or a different checkmark to record his or her view on each of the questions asked. This has permitted as many as four replies on one questionnaire.

Probably the questionnaire this year was a bit too complicated and tried to cover too much ground. I was eager to get as much of the thinking of my constituents as possible—but to ask their views on almost 50 separate questions, was, I fear, something of an imposition.

In such a questionnaire, one, of course, cannot rightly expect full or adequate statements of a person's views on issues which are very complex. But one can determine general trends in public thinking.

The replies tabulated below speak for themselves. But it may be worthwhile



Digest of CONGRESSIONAL PROCEEDINGS

OF INTEREST TO THE DEPARTMENT OF AGRICULTURE

OFFICE OF
BUDGET AND FINANCE

(For Department
Staff Only)

Issued July 1, 1960
For actions of June 30, 1960
86th-2d, No. 122

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HIGHLIGHTS: House passed: Sugar bill; bill to amend Fair Labor Standards Act. House agreed to conference report on general Government matters appropriation bill. House received conference report on independent offices appropriation bill. House received veto message on pay bill. Senate agreed to concurrent resolution for adjournment July 2-Aug. 8. Senate agreed to House amendments to color additives bill. Senate passed State-Justice-Judiciary appropriation bill. Senate passed bill to increase maximum per diem allowances. Senate committee reported nomination of Stephens to OGC. Sen. Magnuson introduced and discussed bill to provide for development of forest roads and trails.

SENATE

June 30, 1960

1. COLOR ADDITIVES. Concurred in the House amendments to S. 2197, to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used. This bill will now be sent to the President. pp. 14059-63
2. APPROPRIATIONS. Passed with amendments H. R. 11666, the State, Justice, Judiciary appropriation bill. Senate conferees were appointed. House conferees have not yet been appointed. pp. 14064-78
Agreed to, 82-4, the conference report on H. R. 11998, the defense appropriation bill, and acted on amendments in disagreement. This bill will now be sent to the President. pp. 14024-35 (See item 19 for House action).

3. TRAVEL. Passed as reported H. R. 5196, which provides as follows: Increases the maximum per-diem allowance for Government employees traveling on official business from \$12 to \$15. Permits reimbursement for cost of parking when incurred by Federal employees in use of private vehicles when on official business. Provides for transfer of authority from the Budget Bureau to the President or his delegate for establishing the per diem rates for civilian employees traveling beyond the limits of the continental U. S. p. 14063
4. TRANSPORTATION. Concurred in the House amendment to S. 1509, to provide "grandfather rights" for certain Alaskan and Hawaiian carriers and freight forwarders. This bill will now be sent to the President. p. 14023
5. RETIREMENT. Concurred in the House amendments to S. 2857, to amend the Civil Service Retirement Act so as to provide for refunds of contributions in the case of annuitants whose length of service exceeds the amount necessary to provide the maximum annuity allowable under such act. This bill will now be sent to the President. pp. 14035-6
6. VETERANS' LOANS. Passed without amendment H. R. 7903, to extend for 2 years the veterans' guaranteed and direct loan program. This bill will now be sent to the President. pp. 14045-6, 14051-3, 14058
7. NOMINATION of Carl J. Stephens, to be General Counsel of this Department, was reported by the Agriculture and Forestry Committee. p. 13990
8. WHEAT. Sen. Carlson inserted and discussed his letter to Secretary Benson recommending a research project on "the relation of wheat to the rest of the economy through all the stages of growing, transporting, storing, distributing, milling, processing and wholesaling and retailing." p. 13986
9. MIGRATORY LABOR. Sen. Kennedy inserted a speech by Sen. Harrison describing the work of his Subcommittee on Migratory Labor. pp. 14010-12
10. FLOOD CONTROL. Sen. Hartke spoke in favor of S. 3625, to establish a Wabash Basin Interagency Water Resources Commission. pp. 14021-2
11. FARM PROGRAM. Sen. Humphrey inserted and discussed his newsletter and a newspaper article criticizing the administration's farm program. pp. 14042-4
12. NATURAL RESOURCES. Sen. Humphrey inserted Izaak Walton League resolutions regarding water and air pollution, management of public lands, Columbia River Basin, shoreline conservation, pesticides coordination, Lake Okeechobee flood control, roads in Superior National Forest, prospecting in Jefferson National Forest, etc. pp. 14038-41
13. LEGISLATIVE PROGRAM. Agreed to, without amendment, 63-26, S. Con. Res. 112, providing "That the two Houses shall adjourn on Saturday, July 2, 1960, and that when they adjourn on said day they stand adjourned until 12 o'clock noon on Monday, August 8, 1960." pp. 13973-89
Sen. Johnson announced that the Senate will consider the veto of the pay bill today, July 1, if the House votes to override. p. 14083

receive compensation at a rate to be fixed by the Secretary, but not in excess of \$50 per diem, including travel time, and while away from their homes or regular places of business may be allowed travel expenses, including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

(c) For the purposes of this section—

(1) The term "health research" shall include, but not be limited to, research, investigations, and studies relating to causes and methods of prevention of accidents, including but not limited to highway and aviation accidents.

(2) The term "participating foreign countries" means those foreign countries which cooperate with the United States in carrying out the purposes of this section.

AUTHORITY OF PRESIDENT

SEC. 5. (a) It is the sense of Congress that the President should use his authority under the Constitution and laws of the United States to accomplish the purposes of section 2 of this joint resolution and in accomplishing such purposes (1) use to the fullest extent practicable foreign currencies or credits available for utilization by the United States, (2) enter into agreements to use foreign currencies and credits available to other nations for use with the agreement of the United States, and (3) use any other foreign currencies and credits which may be made available by participating foreign countries.

(b) To carry out the purposes of section 2 of this joint resolution the President, in cooperation with participating foreign countries, is authorized to encourage, support, and promote the planning and conduct of, and training for, research investigations, experiments, and studies in the United States and in participating foreign countries relating to the causes, diagnosis, treatment, control, and prevention of diseases and impairments of mankind (including nutritional and other health deficiencies) or to the rehabilitation of the handicapped.

(c) To carry out his responsibilities under this joint resolution the President may—

(1) establish and maintain fellowships in participating foreign countries;

(2) make financial grants to establish and maintain fellowships, and for other purposes, to public institutions and agencies and to nonprofit private institutions and agencies, and to individuals in participating foreign countries, or contract with such institutions, agencies, or individuals without regard to sections 3648 and 3709 of the Revised Statutes of the United States;

(3) make grants or loans of equipment, medical, biological, physical, or chemical substances or other materials, for use by such institutions, agencies, or individuals;

(4) furnish technical assistance and advice to such institutions or agencies and in carrying out such purposes may pay the compensation and expenses of scientists and experts from the United States and other participating foreign countries;

(5) facilitate the interchange among participating foreign countries of scientists and experts (including the payment of travel and subsistence for such scientists and experts when away from their places of residence);

(6) cooperate and assist in the planning and conduct of research, research planning, and research training programs and projects by groups engaged in, or concerned with, research or research training endeavors in the health sciences, and, through financial grants or other appropriate means, assist in special research, research planning, or research training projects conducted by or under the auspices of such groups where they

can effectively carry out such activities contemplated by this joint resolution;

(7) encourage and support international communication in the sciences relating to health by means of calling or cooperating in the convening, and financing or contributing to the financing of the expenses of, international scientific meetings and conferences; and provide, or arrange for the provision of, translating and other services, and issue or finance publications, leading to a more effective dissemination of relevant scientific information with respect to research conducted in the United States or participating foreign countries.

(d) The activities authorized in this section shall not extend to the support of public health, medical care, or other programs of an operational nature as contrasted with research and research training nor shall any of the grants authorized by this section include grants for the improvement or extension of public health administration in other countries except for necessary research and research training in the science of public health and public health administration.

(e) The President is authorized, to the extent he deems it necessary to carry out the purposes of section 2 of this joint resolution, to employ experts and consultants or organizations thereof, as authorized by section 15 of the Administrative Expenses Act of 1946 (5 U.S.C. 55a), and create a committee or committees to be composed entirely of persons who are citizens of the United States to advise him in the administration of this joint resolution; individuals so employed and members of committees shall be entitled to receive compensation at a rate to be fixed by the President, but not to exceed \$50 per diem, including travel time, and while away from their homes or regular places of business they may be allowed travel expenses including per diem in lieu of subsistence, as authorized by section 5 of the Administrative Expenses Act of 1946 (5 U.S.C. 73b-2) for persons in the Government service employed intermittently.

(f) The President may delegate any authority vested in him by this section to the Secretary of Health, Education, and Welfare. The Secretary may from time to time issue such regulations as may be necessary to carry out any authority which is delegated to him under this section, and may delegate performance of any such authority to the Surgeon General of the Public Health Service, the Director of the Office of Vocational Rehabilitation, the Chief of the Children's Bureau, or other subordinates acting under his direction.

(g) In order to carry out the purposes of section 2 of this joint resolution, and subject to section 1415 of the Supplemental Appropriation Act, 1953, the President may use or enter into agreements with foreign nations or organizations of nations to use the foreign currencies which accrue under title I of the Agricultural Trade Development and Assistance Act of 1954, and the Mutual Security Act of 1954, or which are otherwise available for utilization by the United States. The President is authorized to agree to the utilization by foreign nations, for programs designed to carry out the purposes of section 2 of this joint resolution in cooperation with the United States, of amounts deposited in special accounts pursuant to section 142(b) of the Mutual Security Act of 1954, to the extent that the amounts in such accounts exceed the requirements of other programs covered by such section 142(b). Such utilization of amounts in special accounts shall be without regard to the second proviso in clause (iii) of such section 142(b).

(h) The President shall transmit to the Congress at the beginning of each regular session, a report summarizing activities un-

der this section and making such recommendations as he may deem appropriate.

(i) For the purposes of this section—

(1) The term "health research" shall include, but not be limited to, research, investigations, and studies relating to causes and methods of prevention of accidents, including but not limited to highway and aviation accidents.

(2) The term "participating foreign countries" means those foreign countries which cooperate with the United States in carrying out the purposes of this section.

OTHER AUTHORITY

SEC. 6. Nothing in this joint resolution shall be construed to repeal or restrict authority vested in the President, the Secretary of State, the Secretary of Health, Education, and Welfare, the Surgeon General of the Public Health Service, or any other officer or agency of the United States by any other provision of law.

Mr. HILL. Mr. President, the House amendment does not change the basic authority originally outlined in the Senate bill. I have cleared the amendment with the distinguished minority leader, the Senator from Illinois [Mr. DIRKSEN], and I move that the Senate concur in the House amendment.

The PRESIDING OFFICER. The question is on the motion of the Senator from Alabama.

The motion was agreed to.

COLOR ADDITIVE AMENDMENTS OF 1960

The PRESIDING OFFICER laid before the Senate the amendment of the House of Representatives to the bill (S. 2197) to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used, which was, to strike out all after the enacting clause and insert:

That this Act may be cited as the "Color Additive Amendments of 1960."

TITLE I—AMENDMENTS TO THE FEDERAL FOOD, DRUG, AND COSMETIC ACT

Definitions

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or"

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

Colors or colored articles—When deemed to be adulterated or misbranded foods, drugs, or cosmetics

Food

SEC. 102. (a) (1) Clause (2) (A) of section 420(a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive".

(2) Section 402(c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

"(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Drugs

(b) (1) Clause (4) of section 501(a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal tar color) is amended to read as follows: "(4) if (A) it is a drug which bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a)."

(2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

"(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706."

Cosmetics

(c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

"(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a)."

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amend-

ed by adding at the end thereof the following new paragraph:

"(e). If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a))."

Regulations to assure safety of color additives for foods, drugs, and cosmetics

SEC. 103. (a) Such Act is further amended by—

(1) repealing subsection (b) of section 406 and striking out the subsection designation "(a)" after "SEC. 406." in such section;

(2) repealing section 504;

(3) repealing section 604; and

(4) amending section 701(e) by (A) striking out "406 (a) or (b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604,"; and (C) inserting the word "or" after "501(b)."

(b) Section 706 of such Act is amended to read as follows:

"LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

"When color additives deemed unsafe

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a) (4), or section 601(e), as the case may be, unless—

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c) for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations of such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

"Listing of colors

"(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on

the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: Provided, however, That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

"(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

"(B) A color additive (1) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

"(C) (1) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced

by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of the paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

"(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to an advisory committee; the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that, in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the

Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of colors

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for issuance, amendment, or repeal of regulations

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection

(b) (5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

"(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing;

"(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f) (2); and

"(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g).

"Fees

"(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

"Exemptions

"(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health."

Confidentiality of trade secrets

SEC. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out "or 704" and inserting in lieu thereof "704, or 706".

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), "404, 406(b), 504, 506, 507, or 604" and inserting in lieu thereof "404, 506, 507, or 706";

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's

guarantee), the word "coal-tar" wherever it appears in such clause, and (2) inserting after the word "color", wherever it appears in such clause, the word "additive"; and

(c) striking out "harmless coloring" in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof "authorized coloring".

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

Definitions

SEC. 201. As used in this title, the term "basic Act" means the Federal Food, Drug, and Cosmetic Act; the term "enactment date" means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

Effective date

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

Provisional listings of commercially established colors

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term "closing date" means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary's judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had

been certified for such use or uses prior to the enactment date, and

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives and particular uses thereof as specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to

section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1) (E) of this subsection; or

(ii) has, pursuant paragraph (1) (C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(D) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing, a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act. A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraph (1) (A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1) (A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

Effect on Meat Inspection and Poultry Products Inspection Acts

SEC. 204. Nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following) or the Poultry Products Inspection Act (21 U.S.C. 451 and the following).

Mr. HILL. Mr. President, I have discussed the amendment with the distinguished minority leader, the Senator from Illinois [Mr. DIRKSEN]. I have also cleared it with the secretary of the Committee on Health, Education and Welfare. I move that the Senate concur in the House amendment.

The PRESIDING OFFICER. The question is on the motion of the Senator from Alabama.

The motion was agreed to.

GOVERNMENT PER DIEM ALLOWANCES FOR EMPLOYEES TRAVELING ON OFFICIAL BUSINESS

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 1791, H.R. 5196.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H.R. 5196) to increase the maximum rates of per diem allowance for employees of the Government traveling on official business, and for other purposes, reported from the Committee on Government Operations, with amendments.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill.

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the committee amendments be considered and agreed to en bloc.

The PRESIDING OFFICER. Is there objection? The Chair hears none, committee amendments are agreed to en bloc.

The amendments agreed to en bloc are as follows:

On page 1, after line 5, to strike out:

"SEC. 2. Section 4 of the Travel Expense Act of 1949 (5 U.S.C. 837) is amended by striking out '6 cents' and inserting in lieu thereof '7 cents', and by striking out '10 cents' and inserting in lieu thereof '12 cents'."

At the beginning of line 10, to change the section number from "3" to "2"; on page 2, after line 3, to insert a new section, as follows:

"SEC. 3. The Director of the Administrative Office of the United States Courts shall promulgate, in accordance with section 604 (a) (7) and section 456 of title 28 of the United States Code, such regulations as he may deem necessary to effectuate the increases provided by this Act."

After line 8, to insert a new section, as follows:

"SEC. 4. The seventh paragraph under the heading 'Administrative Provisions' in the Senate section of the Legislative Branch Appropriation Act, 1957 (2 U.S.C. 68b), is amended by striking out '\$12' and inserting in lieu thereof '\$15'."

After line 13, to insert a new section, as follows:

"SEC. 5. (a) Section 3 of the Travel Expense Act of 1949, as amended (5 U.S.C. 836), is hereby further amended (1) by striking out the words 'by the Director of the Bureau of the Budget' appearing before the first proviso, and by substituting therefor the following: 'by the President or his delegate (who may be the Director of the Bureau of the Budget or any other officer of the Government)' and (2) by striking out the proviso at the end of such section and inserting in lieu thereof the following proviso: 'And provided further, That where due to the unusual circumstances of a travel assignment the maximum per diem allowance would be much less than the amount required to meet the actual and necessary expenses of the trip, the heads of departments and establishments may, in accordance with regulations promulgated by the Director, Bureau of the Budget, pursuant to section 7, prescribe conditions under which reimbursement for such expenses may be authorized on an actual expense basis not to exceed a maximum amount to be specified in the travel authorization, but in any event not to exceed, for each day in travel status, (1) the amount of \$25, within the limits of the continental United States, or (2) the sum of the maximum per diem allowance plus \$10, for travel outside such limits.'

"(b) Section 5 of the Administrative Expenses Act of 1946, as amended (5 U.S.C. 73b-2), is hereby further amended (1) by striking out the words 'by the Director of the Bureau of the Budget' appearing before the proviso, and (2) by striking out the proviso at the end of such section and inserting in lieu thereof the following proviso: 'Provided, That where due to the unusual circumstances of a travel assignment the maximum per diem allowance would be much less than the amount required to meet the actual and necessary expenses of the trip, the heads of departments and establishments may, in accordance with regulations promulgated by the Director, Bureau of the Budget, pursuant to section 7 of the Travel Expense Act of 1949, as amended (5 U.S.C. 840), prescribe conditions under which reimbursement for such expenses may be authorized on an actual expense basis not to exceed a maximum amount to be specified in the travel authorization, but in any event not to exceed, for each day in travel status, (1) the amount of \$25, within the limits of the continental United States, or (2) the sum of the maximum per diem allowance plus \$10, for travel outside such limits.'

"(c) Section 48 of the Alaska Omnibus Act (73 Stat. 141; 48 U.S.C. note prec. sec. 23) shall not apply to the amendments made by this section."

On page 4, after line 10, to insert a new section, as follows:

"SEC. 6. Section 3 of the Act of July 30, 1946 (22 U.S.C. 287o) is amended so that the last proviso will read as follows: 'Provided, however, That he may be paid transportation and other expenses as authorized by section 5 of the Administrative Expenses Act of 1946 as amended (5 U.S.C. 73b-2).'"

After line 16, to insert a new section, as follows:

"SEC. 7. Section 5 of the Act of July 30, 1946 (22 U.S.C. 287q) is amended so that the sentence relating to transportation and subsistence expenses will read as follows: 'The Department of State may pay their transportation and other expenses as authorized by section 5 of the Administrative Expenses Act of 1946 as amended (5 U.S.C. 73b-2), for the period of actual attendance and of necessary travel.'"

And, after line 23, to insert a new section, as follows:

"SEC. 8. Section 801 of the United States Information and Educational Exchange Act of 1948 (22 U.S.C. 1471) is amended in subsection (6) so that the portion following the semicolon in the last sentence will read as follows: 'but he may be paid his transportation and other expenses, as authorized by section 5 of the Administrative Expenses Act of 1946, as amended (5 U.S.C. 73b-2).'"

The amendments were agreed to.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the statement of purpose behind the bill be inserted at this point in the RECORD.

There being no objection, the statement was ordered to be printed in the RECORD, as follows:

STATEMENT OF PURPOSE

Section 1 of the bill proposes to increase the maximum rates of per diem allowance for employees of the Government traveling on official business from \$12 to \$15 per day.

Section 2 would permit reimbursement for the actual cost of parking fees when incurred by Federal employees in the utilization of privately owned vehicles when engaged on official business.

Sections 3 and 4 of the amended bill were included so as to bring employees of the U.S. courts, and Senators and employees of the U.S. Senate, under the provisions of sections 1 and 2.

Section 5 provides for the transfer of authority from the Bureau of the Budget to the President or his delegate for establishing the per diem rates for civilian employees traveling beyond the limits of the continental United States. Sections 5 through 8 would extend the provisions of sections 1 and 2 to all persons traveling on official business either in the United States or abroad, except in Alaska and Hawaii. Special statutes applying to per diem allowances in Alaska and Hawaii are not affected by the provisions of the bill.

The PRESIDING OFFICER. The bill is open to further amendment. If there be no amendment to be proposed, the question is on the engrossment of the amendments and the third reading and passage of the bill.

The amendments were ordered to be engrossed and the bill to be read a third time.

The bill was read the third time and passed.

THE GREAT RIVER ROAD

Mr. HUMPHREY. Mr. President, I introduce, for appropriate reference, a bill to provide assistance to the ten States bordering the Mississippi River in the construction of the Great River Road: Arkansas, Illinois, Iowa, Kentucky, Louisiana, Minnesota, Mississippi, Missouri, Tennessee, and Wisconsin. This road would follow along the banks of the Mississippi River, a river of unequalled length in our land. Running 2,470 miles from Lake Itasca, Minn., to the Gulf of Mexico, this is one of our most beautiful river valleys. This road, cutting through the heartland of our country would join Canada with the Gulf of Mexico at Louisiana and would connect with Florida in the East and Texas in the West.

This road when completed will be one of the most important arteries in the American highway system. It will provide a less difficult and much more historical, scenic, and cultural route by which the American people can travel from Canada to the Gulf, the breadth of our country. This would also be a route which our neighbors will find easily accessible and well worth traveling, thus bringing more visitors from our nearest lands. It is, therefore, a road which will not only benefit our own people, but will provide an opportunity to promote friendship with our neighbors to the North and to the South.

Originally, the Mississippi River Parkway or Great River Road was conceived as a Federal parkway similar to the Blue Ridge and Natchez Trace Parkways. In August 1949, Congress instructed the Bureau of Public Roads and the National Park Service to make a survey and study of the route. A joint report by the Secretary of Commerce and the Secretary of the Interior was presented on November 28, 1951, entitled "Parkway for the Mississippi"; a new idea in interstate highway development emerged, the Federal-aid parkway. Utilization of existing highways which meet the standards of parkway conditions, and new locations under favorable conditions are characteristic. Many of the roads need only widening to be adequate for foreseeable traffic.

The general locations of State highways along the proposed route are such that it is possible to link them all together and to obtain nearly complete control of access without disrupting the local highway patterns. These highways are necessary parts of the highway system in each State. An entirely new highway would in many parts duplicate existing highways which could be made adequate for future use. Many of the most scenic routes are already located on the present highways.

There are, however, many miles of land close to the river on which no highways presently exist. Then, too, recreational use of the parkway will increase as it becomes better known. The need for adequate land and facilities is as necessary as the road itself. It is for locations such as these, that section (b) of my bill would propose an appropriation of \$2 million for the fiscal year ending June 30, 1962 and a like sum for the

fiscal year ending June 30, 1963. These sums would be used to purchase rights-of-way, to construct roads, recreational facilities, rest areas, parking areas at historical locations, and to reconstruct roads and facilities which with some work can be adequately used.

Section (a) of this bill provides that the 10 States through which the road will pass may use up to 10 percent of the A-B-C funds already allotted to each State for the purchase of rights-of-way, construction, reconstruction, and improvement of the Great River Road.

This bill was drafted in cooperation with the Mississippi River Parkway Planning Commission, a group which has been working very hard to complete plans for the road. In submitting this bill, I realize that it is too late in the session to expect any action to be taken. But, it is my hope that this bill will be widely circulated and sufficient interest in it generated to make possible its passage in the next Congress.

The PRESIDING OFFICER. The bill will be received and appropriately referred.

The bill (S. 3794) to provide assistance to certain States bordering the Mississippi River in the construction of the Great River Road, introduced by Mr. HUMPHREY, was received, read twice by its title, and referred to the Committee on Public Works.

DEPARTMENTS OF STATE, JUSTICE AND THE JUDICIARY APPROPRIATIONS, 1961

Mr. MANSFIELD. Mr. President, I ask unanimous consent that the Senate proceed to the consideration of Calendar No. 1847, H.R. 11666.

The PRESIDING OFFICER. The bill will be stated by title for the information of the Senate.

The LEGISLATIVE CLERK. A bill (H.R. 11666) making appropriations for the Departments of State and Justice, Judiciary, and related agencies for the fiscal year ending June 30, 1961, and for other purposes.

The PRESIDING OFFICER. Is there objection to the present consideration of the bill?

There being no objection, the Senate proceeded to consider the bill, which has been reported from the Committee on Government Operations with amendments.

Mr. MANSFIELD. Mr. President, I suggest the absence of a quorum.

The legislative clerk proceeded to call the roll.

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the order for the quorum call be rescinded.

The PRESIDING OFFICER. Without objection, it is so ordered.

Mr. JOHNSON of Texas. Mr. President, I ask unanimous consent that the committee amendments be considered and agreed to en bloc.

The PRESIDING OFFICER. Without objection, it is so ordered.

The committee amendments agreed to en bloc are as follows:

Under the heading "Title I—Department of State—Administration of Foreign Af-

fairs—Salaries and Expenses," on page 2, line 18, after the word "exceed", to strike out "nine, of which two shall be for replacement only" and insert "thirteen", and on page 3, line 18, after the word "aids", to strike out "\$113,500,000" and insert "\$117,377,000".

Under the subhead "Representation Allowances", on page 4, line 8, after "(22 U.S.C. 1131)", to strike out "\$835,000" and insert "\$875,000".

Under the subhead "Extension and Remodeling, State Department Building", on page 6, line 17, after the word "expended", to strike out "\$225,000" and insert "\$596,200".

Under the subhead "Missions to International Organizations", on page 7, line 12, after the word "chauffeurs", to strike out "\$1,835,000" and insert "\$1,865,000".

Under the subhead "International Tariff Negotiations", on page 8, line 12, after the word "including", to insert "purchase of not to exceed one passenger motor vehicle, and"; in line 13, after the word "exceed", to strike out "\$1,000" and insert "\$5,000", and in line 16, after the word "entertainment", to strike out "\$600,000" and insert "\$700,000".

The amendment was agreed to.

The next amendment was, under the subhead "Operation and Maintenance", on page 10, at the beginning of line 4, to strike out "\$1,840,000" and insert "\$1,982,000".

Under the subhead "Construction", on page 10, line 18, after "1944", to strike out "\$2,000,000" and insert "\$9,000,000", and on page 11, line 6, after the word "State", to insert a colon and "Provided further, That \$5,000,000 of this appropriation shall be effective only upon the enactment into law of H.R. 12263, Eighty-sixth Congress, second session, or similar legislation."

Under the subhead "Educational Exchange—International Educational Exchange Activities", on page 14, line 4, after the word "amended", to strike out "\$23,210,000" and insert "\$28,200,000", and in line 7, after the word "exceed", to strike out "\$1,437,500" and insert "\$1,700,000".

On page 15, after line 17, to insert:

"CENTER FOR CULTURAL AND TECHNICAL INTERCHANGE BETWEEN EAST AND WEST

"To enable the Secretary of State to provide for carrying out the provisions of the Center for Cultural and Technical Interchange Between East and West Act of 1960, by grant to any appropriate agency of the State of Hawaii, \$10,000,000."

At the top of page 16, to insert:

"PRESENTATION OF A STATUE TO URUGUAY

"For expenses necessary to provide for a statue of George Washington, to be presented to the people of Uruguay, as authorized by the Act of September 21, 1959 (Public Law 86-345), \$18,000."

On page 16, after line 5, to insert:

"PAN AMERICAN HEALTH ORGANIZATION BUILDING SITE

"For necessary expenses of carrying out the provisions of the Act of March 28, 1960 (Public Law 86-395) authorizing the acquisition of land for conveyance, without consideration, to the Pan American Health Organization for use as a headquarters site, \$875,000, to be transferred to the General Services Administration."

On page 16, after line 12, to insert:

"PAYMENT TO THE GOVERNMENT OF JAPAN FOR BONIN ISLANDERS' CLAIMS

"For payment to the Government of Japan for settlement of all claims of displaced residents of the Bonin Islands, as authorized by the Act of June 1, 1960 (Public Law 86-486), \$6,000,000."

Under the subhead "General Provisions—Department of State", on page 17, after line 22, to insert a new section, as follows:

"SEC. 107. It is the sense of the Senate that in the administration of section 414 of the

Senate July 1, 1960

11. TRANSPORTATION. Both Houses agreed to the conference report on H. R. 11135, to aid in the development of a coordinated system of transportation for the National Capital region; to create a temporary National Capital Transportation Agency; etc. This bill will now be sent to the President. pp. 14300-1, 14337
12. FLOOD CONTROL. Both Houses agreed to the conference report on H. R. 7634, the omnibus flood control and rivers and harbors bill, and acted on amendments in disagreement. This bill will now be sent to the President. pp. 14405-9, 14312-20
13. COLOR ADDITIVES. Sen. Javits inserted the conclusions and recommendations of a study issued by the White House on the use of color additives in food, and his motion was tabled to reconsider the vote by which S.2197, to regulate the use of color additives in food, was passed. pp. 14301-2
14. RECLAMATION. Passed as reported S. 2195, to authorize the Secretary of the Interior to construct the western division of the Dalles Federal reclamation project, Ore. pp. 14419-20
15. SMALL BUSINESS. Passed with amendments H. R. 11207, to authorize additional funds for small-business loans and to encourage additional use of small business by Government contracting agencies. pp. 14424-7
16. PUBLIC HEALTH. Passed as reported H. R. 6871, to amend the Public Health Service Act so as to authorize project grants for graduate training in public health. pp. 14376-7
17. CONTRACTS; PURCHASING. Sen. Douglas criticized purchasing policies of Government agencies, particularly the purchase of supplies by agencies when surplus supplies were already available in the Government, and inserted several items on this matter. pp. 14231-6

HOUSE

18. FOREST ROADS. Received the conference report on H. R. 10495, authorizing appropriations for highway construction for fiscal 1962 and 1963, including forest highways and forest development roads and trails (pp. 14338-9). As reported by the conferees the bill authorizes \$33,000,000 for forest highways for each of the fiscal years 1962 and 1963, and \$35,000,000 and \$40,000,000 for the fiscal years 1962 and 1963, respectively, for forest development roads and trails, and authorizes an additional \$500,000 for construction of road on forest land in Ga. (H. Rept. 2080)
19. CROP INSURANCE; LANDS; CONSERVATION. The Agriculture Committee voted to report (but did not actually report) the following bills: p. D650
H. R. 5743, to amend the Federal Crop Insurance Act to permit inclusion of administrative costs in insurance premiums;
H. R. 10784 (amended), to provide that the payment for the lands covered by the Act of September 9, 1959 (Keosauqua lands), may be made on a deferred basis;
H. R. 11917 (amended), to authorize the Secretary of Agriculture to convey certain lands in Lassen County, California, to the city of Susanville, California;
H. R. 12849 (amended), to protect farm and ranch operators making certain land use changes under the Great Plains conservation program and the soil bank program against loss of cropland acreage and acreage allotments;

H. R. 12860 (amended), authorizing the Secretary of Agriculture to convey certain lands to Auburn University, Auburn, Ala.;

S. 2772, to authorize the Secretary of Agriculture to convey land in the town of Cascade, El Paso County, Colorado;

S. 3665, to authorize the Secretary of Agriculture to grant an easement over certain lands to the trustees of the Cincinnati Southern Railway, their successors and assigns;

S. 3070, to provide for the removal of restriction on use with respect to certain lands in Morton County, North Dakota, conveyed to the State of North Dakota on July 20, 1955;

S. 2919, to provide that the Secretary of the Smithsonian Institution shall study and investigate the desirability and feasibility of establishing and maintaining a national tropical botanic garden;

S. 1857, to establish minimum standards for the exportation of grapes and plums.

20. WATERSHEDS. The Public Works Committee approved watershed projects for Big Prairie and French Creeks, Ala.; Mill Run, Penn.; and Town Fork Creek, N. C. p. 14308

The "Daily Digest" states that the Agriculture Committee approved a watershed project in Texas and one in Indiana. p. D650

21. PROPERTY IMPORTS. By a vote of 124 to 61, agreed to a motion by Rep. Flynt to strike out the enacting clause on H. R. 9996, to amend the Federal Property and Administrative Services Act of 1949 so as to prescribe procedures to insure that foreign excess property which is disposed of overseas will not be imported into the U. S. to the injury of the economy of this country. This action has the effect of killing the bill. pp. 14323-37

22. FLOOD CONTROL. The Public Works Committee reported with amendment H. R. 2185, to authorize modification of local participation in flood control projects in depressed areas (H. Rept. 2067). p. 14374

23. RECREATION. Passed as reported H. R. 900, to provide that 75% of all moneys derived by the U. S. from certain recreation activities in connection with land acquired for flood control and other purposes shall be paid to the State. p. 14349

24. GOVERNMENT ORGANIZATION. Rep. Lindsay inserted a speech by Gov. Rockefeller which includes the Governor's recommendations as to reorganization in the executive branch. pp. 14359-62

25. DEPRESSED AREAS; INDUSTRIAL LOANS. Rep. Flood urged consideration of a bill to "allow banks and lending institutions to rediscount their industrial mortgages with the Federal Government following generally the same pattern as Fannie Mae mortgages" and the establishment of an Area Redevelopment Administration which he says would be of assistance to a self-help program for depressed area redevelopment. pp. 14367-72

26. COCONUT MEAT. Both Houses received and the Senate adopted the conference report on H. R. 11748, to continue until the close of June 30, 1961, the suspension of duties on metal scrap, which as amended by the Senate creates a specific tariff classification for certain imported coconut meat (H. Rept. 2074). pp. 14340, 14376

Mr. BIBLE. I think the agency certainly could take proper recognition of such action.

Mr. President, I fully and wholeheartedly endorse the bill. I think it is a step in the right direction. It moves into the field of mass transportation in the Washington metropolitan area.

Mr. President, I move that the Senate agree to the conference report.

The PRESIDING OFFICER. The question is on agreeing to the conference report.

The report was agreed to.

MESSAGE FROM THE HOUSE

A message from the House of Representatives, by Mr. Bartlett, one of its reading clerks, announced that the House had agreed to the report of the committee of conference on the disagreeing votes of the two Houses on the amendments of the Senate to the bill (H.R. 12232) making appropriations for the legislative branch for the fiscal year ending June 30, 1961, and for other purposes.

The message also announced that the House had passed a bill (H.R. 12475) for the relief of Claude L. Wimberly, in which it requested the concurrence of the Senate.

ENROLLED BILLS SIGNED

The message further announced that the Speaker had affixed his signature to the following enrolled bills, and they were signed by the President pro tempore:

S. 598. An act for the relief of Anthony Di Giovanni;

S. 1409. An act for the relief of Donald B. Thurston and other employees of the Fish and Wildlife Service;

S. 1454. An act for the relief of Keitha L. Baker;

S. 1965. An act to make uniform provisions of law with respect to the terms of office of the members of certain regulatory agencies;

S. 2197. An act to protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used; and

S. 3125. An act for the relief of Robert William Neal, Robert J. Naumann, Charles LeRoy Van Slyke, and Franklin Jordan.

HOUSE BILL REFERRED

The bill (H.R. 12475) for the relief of Claude L. Wimberly, was read twice by its title and referred to the Committee on the Judiciary.

COLOR ADDITIVE AMENDMENTS OF 1960

Mr. JAVITS. Mr. President, I move to reconsider the vote by which the Senate yesterday concurred in the amendment of the House to S. 2197, to protect the public health by amending the Federal Food, Drug, and Cosmetic Act. On that motion, I ask recognition.

The PRESIDING OFFICER. The Chair recognizes the Senator from New York.

Mr. JAVITS. Mr. President, I think it is essential that the record be made clear upon this measure. It was approved in my absence yesterday, but quite in good faith on the part of those who may probably have believed that I had agreed to it, although I actually had not agreed to it.

The bill proposes to amend the Food, Drug, and Cosmetic Act by providing that color additives and various types of food, drugs, and cosmetics should be subject to the same tests as other substances which are covered by another law.

The main problem which is raised in respect to all this legislation occurs in paragraph B of section 706 of the law, which deals with substances which may induce cancer in man or animal.

This is a very serious matter, of course, and it properly commends itself to our grave concern.

By means of this measure the Secretary of Health, Education, and Welfare is not only given broad authority, but is given mandatory direction, to see that any color additive which, upon tests of man or animals, is found to have this effect, or if it is found that it could possibly have this effect, is barred from use.

Those who manufacture pharmaceuticals and have very substantial employment and very substantial plants in the State of New York, take very serious exception to feasibility of this kind of very strict and mandatory standard, from the point of view of whether it can be carried out without so greatly inhibiting normal and perfectly safe practices in the pharmaceutical industry as to very seriously hurt their businesses.

In that connection, we have a very important piece of evidence, because this subject has been examined at the White House level; and in that connection I read now from a statement issued on May 14 from the White House:

THE WHITE HOUSE, May 14, 1960.

The White House today made public the report of a study of certain aspects of the use of chemicals and drugs as food additives, which the President requested to be made by the Departments of Agriculture, and Health, Education, and Welfare, and the President's Science Advisory Committee.

In making this study, the Science Advisory Committee convened a special panel of experts and consulted scientists from the Agriculture, and Health, Education, and Welfare Departments and also outside Government circles.

Findings of the study were approved by the President's Special Assistant for Science and Technology, Dr. George B. Kistiakowsky, and also concurred in by the Departments of Agriculture, and Health, Education, and Welfare.

The report describes the complex nature of the scientific issues involved in protecting the food supply from added cancer-producing substances. It suggests areas of research and also recommends improved administrative procedures.

Mr. President, I ask unanimous consent to have printed at this point in the RECORD the conclusions and recommendations set forth in the report.

There being no objection, the excerpt from the report was ordered to be printed in the RECORD, as follows:

CONCLUSIONS AND RECOMMENDATIONS

The rapidly increasing number of new chemicals potentially useful in agriculture

and food production demand vigilant and careful scrutiny of the compounds offered in order to safeguard the consumer from those that may present carcinogenic and other toxic hazards.

In applying the provisions of section 409(c)(3) of the Food Additives Amendment of the Food, Drug, and Cosmetic Act, the enforcing agency must employ the "rule of reason"¹ based on scientific judgment in order to carry out the intent of the Congress to protect the public from the possibility of increasing cancer risks through the diet.

The definition of a carcinogen implicit in the language of section 409(c) requires discretion in its interpretation because so many variables enter into a judgment as to whether a particular substance is or is not carcinogenic.

It is to be emphasized that the present difficulty in establishing whether there are permissible levels for certain possibly carcinogenic food additives is accentuated by the limited relevant scientific information available. From the experience obtained in animal experiments and study of humans who have been exposed to carcinogens in the course of their work such as cited above, the panel believes that the probability of cancer induction from a particular carcinogen in minute doses may be eventually assessed by weighing scientific evidence as it becomes available.

The special emphasis placed by the Congress on the protection of the public from the dangers resulting from the addition of possible carcinogens to food calls for prudent administration of section 409(c) of the Food Additives Amendment of the Food, Drug, and Cosmetic Act. Since an area of administrative discretion based on the rule of reason is unavoidable if the clause is to be workable, it is essential that this discretion be based on the most informed and expert scientific advice available. Until the causes of carcinogenesis are better understood, each situation must be judged in the light of all applicable evidence. In this way the protection of public health can best be assured.

Accordingly, the following recommendations are made:

1. That the Secretary of Health, Education, and Welfare appoint a board advisory to him to assist in the evaluation of scientific evidence on the basis of which decisions have to be made prohibiting or permitting the use of certain possibly carcinogenic compounds.

The advisory board should be composed of scientists from the National Cancer Institute, the Food and Drug Administration, the U.S. Department of Agriculture, and the scientists outside of Government from a panel nominated by the National Academy of Sciences.

It would be the function of the board to weigh evidence and to make recommendations to the Secretary of the Department of Health, Education, and Welfare on the basis of available scientific data, both on applications for approval of new food additives and in all cases where the withdrawal of a prior approval or sanction is under consideration. The board would consider among other matters:

(a) whether or not the tests for carcinogenicity are appropriate and reasonable,

(b) whether the substance is or is not in reality carcinogenic as determined histopathologically or by other criteria,

(c) whether addition of the substance to agricultural products would result in a concentration of the substance above the natural background level of such substance,

¹ "Every statute must be interpreted in the light of reason and common understanding to reach the results intended by the legislature." Opinion handed down by Chief Justice Warren in *Rathburn v. U.S.* (355 U.S. 107 at 109).

(d) what assay techniques are appropriate to determine whether a specific carcinogen is present in food.

It would also be the function of this board to review from time to time its recommendations and to modify them in the light of new scientific knowledge. Further, the board would assume the responsibility of recommending to the Secretary of Health, Education, and Welfare specific research problems to be undertaken to provide necessary scientific data.

2. If existing legislation does not permit the Secretary of Health, Education, and Welfare to exercise discretion consistent with the recommendations of this report, it is recommended that appropriate modifications in the law be sought.

3. Because of the limited scientific information available relevant to the effects of possible carcinogenic food additives, it is recommended that:

(a) Proportionately greater emphasis be placed by Government agencies on the study of representative carcinogens in a variety of animal species in an attempt to define dose-response relations. It must be recognized from the very nature of such research that definitive answers useful in extrapolation to man may not be expected for many years to come. The applicability of such research to the problems discussed in this report will be furthered by studies carried out on large groups of animals.

(b) Studies be increased on the possible carcinogenic action of substances to which numbers of individuals have been regularly exposed and that these studies be related to the incidence of cancer in the exposed individuals. Retrospective studies should also be made of patients who have received a variety of chemical compounds, in the course of treatment of disease, which are subsequently suspected of being carcinogenic.

4. Research be expanded also by the Department of Agriculture, by the State Agricultural Experiment Stations, and by industry to discover additional safe and effective materials for the production and processing of foods.

Dr. Detlev W. Bronk, chairman, president, Rockefeller Institute and president, National Academy of Sciences.

Dr. Robert F. Loeb, vice chairman, bard professor of medicine, Columbia University—on leave.

Dr. Edwin B. Astwood, professor of medicine, Tufts University School of Medicine, New England Center Hospital.

Dr. Alfred Gelhorn, director of the Institute of Cancer Research and professor of medicine, Columbia University.

Dr. J. George Harrar, vice president, the Rockefeller Foundation.

Dr. Harold C. Hodge, professor of pharmacology and toxicology, University of Rochester.

Dr. James G. Horsfall, director, the Connecticut Agricultural Experiment Station.

Dr. C. N. Hugh Long, sterling professor of physiology, Yale University.

Dr. C. Chester Stock, scientific director, Sloan-Kettering Institute for Cancer Research.

Consultant: Mr. Charles S. Rhyne, Rhyne & Rhyne, Washington, D.C.

Technical assistant: Dr. Frederic Holtzberg, the President's Science Advisory Committee, the White House.

Mr. JAVITS. Mr. President, the substance of the conclusions set forth in the report is that it states that authority such as that conferred by the amendment—and I have moved to have the vote on the amendment reconsidered—should be used and applied within the "rule of reason." It is intimated that otherwise the measure could be applied very arbitrarily and would not work out

in the way its authors intended or in the way they designed it to work.

Mr. DIRKSEN. Mr. President, will the Senator from New York yield to me?

Mr. JAVITS. Of course.

Mr. DIRKSEN. Mr. President, this matter has been of considerable interest to me. I have discussed it with the Secretary of Health, Education, and Welfare. He says that even if the Delaney amendment were deleted from the legislation, they would still have to apply that general principle, and that they do apply it on the advice of the National Institutes of Health.

They tell me that both the Department of Health, Education, and Welfare and private industries can live with this legislation, and that the rule of reason will prevail. I think that is the manner in which most of those who have come to discuss it, particularly the advisers of some of the commercial interests, have approached it.

Mr. JAVITS. I thank the Senator from Illinois. I point out that the assurance the Senator from Illinois has just given us, and which I hope very much will be joined in by the chairman of the committee, the Senator from Alabama [Mr. HILL], is a caveat to our own agency to apply the rule of reason. I yield to no one in my anxiety to have the law applied to the full, in terms of public health and safety. But at the same time we do not want the application of the law to "go overboard". We wish it to be fair.

So I have moved that the vote by which the amendment was agreed to be reconsidered, in order to afford an opportunity to make a matter of record this position on the part of the Government agencies.

Mr. HILL. Mr. President, will the Senator from New York yield?

Mr. JAVITS. I yield.

Mr. HILL. Mr. President, after consultations with Secretary Flemming, of the Department of Health, Education, and Welfare, I wish to state that I agree with what the Senator from Illinois [Mr. DIRKSEN], has said. I also wish to state that the report of the group of scientists, under date of May 14, 1960, to which the Senator from New York has referred, did not recommend repeal of the Delaney amendment, as that amendment is now carried in the Food Additives Act of 1958, but did recommend that the Secretary of Health, Education, and Welfare appoint a board, advisory to him, to assist in the evaluation of scientific evidence, on the basis of which decisions have to be made as to prohibiting or permitting the use of certain carcinogenic compounds.

I may say that the amendment to which we agreed last night not only provides for such an advisory board—they use the term "advisory committee," but an advisory board is the same thing—but gives to anyone who may feel that he needs some redress the right to have such an advisory committee consider the matter.

Mr. JAVITS. Mr. President, will the Senator from Alabama then join in the assurance given by the distinguished Senator from Illinois [Mr. DIRKSEN], namely, that, fully consistent with

health and safety—and all of us are absolutely committed to guarding and safeguarding them in every possible way, he, too, feels that the legislative record here should show clearly that the recommendation as to the application of the rule of reason by the enforcing agency is expected to be applied?

Mr. HILL. I would say so.

Mr. JAVITS. Mr. President, I understand that the Senator from Alabama proposes to move to lay on the table the motion—

Mr. HILL. Mr. President, I do not wish to interrupt the remarks of the Senator from New York. But following his remarks, I intend to make that motion.

Mr. JAVITS. I shall conclude my remarks in just a moment.

I understand that the Senator from Alabama will move to lay on the table the motion to reconsider the vote by which the amendment was agreed to, as if it had been done on yesterday.

Again, I wish to express my appreciation to the Senator from Alabama. I think among all the chairmen of Senate committees, the Senator from Alabama needs yield to no one as regards his fairness and his very great consideration for all of us who serve with him.

Because we had these objections from those who have a serious interest in the matter, and because it was possible to make the record clear without prejudicing the legislation—certainly I never would wish to do that—I am grateful to him for having facilitated this effort.

Mr. HILL. Mr. President, I thank the Senator from New York for his very kind and generous remarks. Certainly no member of the Committee on Labor and Public Welfare is more cooperative or more helpful in connection with matters pertaining to the health of the people than is the distinguished Senator from New York.

Mr. JAVITS. I thank the Senator from Alabama.

Mr. President, Representative DELANEY has fought a long, hard battle in connection with this matter. I know him very well; he is from New York. I think all of us are indebted to him, too, for the way in which he has carried on this effort to assure the health of the people, as regards the use of these substances.

Mr. President, I yield the floor.

Mr. HILL. Mr. President, I move that the motion to reconsider be laid on the table.

The PRESIDING OFFICER. The question is on agreeing to the motion of the Senator from Alabama to lay on the table the motion that the vote by which the amendment was agreed to be reconsidered.

The motion to lay on the table was agreed to.

TOMMY MORGANO

Mr. McCLELLAN. Mr. President, I send to the desk a resolution, and ask for its immediate consideration.

The PRESIDING OFFICER. The resolution will be stated.

Mr. McCLELLAN. Mr. President, I ask unanimous consent to dispense with the reading of the resolution.

Public Law 86-618
86th Congress, S. 2197
July 12, 1960

AN ACT

74 STAT. 397.

To protect the public health by amending the Federal Food, Drug, and Cosmetic Act so as to authorize the use of suitable color additives in or on foods, drugs, and cosmetics, in accordance with regulations prescribing the conditions (including maximum tolerances) under which such additives may be safely used.

Be it enacted by the Senate and House of Representatives of the United States of America in Congress assembled, That this Act may be cited as the "Color Additive Amendments of 1960".

Color Additive
Amendments of
1960.

TITLE I—AMENDMENTS TO THE FEDERAL FOOD,
DRUG, AND COSMETIC ACT

DEFINITIONS

SEC. 101. Section 201, as amended, of the Federal Food, Drug, and Cosmetic Act is further amended as follows:

52 Stat. 1040;
72 Stat. 1784.
21 USC 321.

(a) Paragraph (s) of such section (defining the term "food additive") is amended by redesignating clause (3) as clause (4), and by inserting immediately before clause (4), as so redesignated, the following new clause:

"(3) a color additive; or".

(b) Paragraph (t) of such section is redesignated and otherwise amended to read as follows:

"(u) The term 'safe', as used in paragraph (s) of this section and in sections 409 and 706, has reference to the health of man or animal."

(c) There is inserted, immediately after paragraph (s) of such section, the following new paragraph:

"(t) (1) The term 'color additive' means a material which—

"(A) is a dye, pigment, or other substance made by a process of synthesis or similar artifice, or extracted, isolated, or otherwise derived, with or without intermediate or final change of identity, from a vegetable, animal, mineral, or other source, and

"(B) when added or applied to a food, drug, or cosmetic, or to the human body or any part thereof, is capable (alone or through reaction with other substance) of imparting color thereto;

except that such term does not include any material which the Secretary, by regulation, determines is used (or intended to be used) solely for a purpose or purposes other than coloring.

"(2) The term 'color' includes black, white, and intermediate grays.

"(3) Nothing in subparagraph (1) of this paragraph shall be construed to apply to any pesticide chemical, soil or plant nutrient, or other agricultural chemical solely because of its effect in aiding, retarding, or otherwise affecting, directly or indirectly, the growth or other natural physiological processes of produce of the soil and thereby affecting its color, whether before or after harvest."

COLORS OR COLORED ARTICLES—WHEN DEEMED TO BE ADULTERATED OR
MISBRANDED FOODS, DRUGS, OR COSMETICS

Food

SEC. 102. (a) (1) Clause (2)(A) of section 402(a), as amended, of such Act (relating to food deemed adulterated by reason of unsafe additives) is further amended by striking out the matter within the parentheses and inserting in lieu thereof the following: "other than

52 Stat. 1040.
21 USC 342.

one which is (i) a pesticide chemical in or on a raw agricultural commodity; (ii) a food additive; or (iii) a color additive”.

52 Stat. 1046.
21 USC 342. (2) Section 402(c), as amended, of such Act (relating to food deemed adulterated by reason of uncertified coal-tar color) is amended to read as follows:

52 Stat. 1058.
21 USC 376. “(c) If it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).”

21 USC 343. (3) Section 403 of such Act (relating to the circumstances under which food is deemed misbranded) is amended by adding at the end thereof the following new paragraph:

“(m) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706.”

Drugs

52 Stat. 1049.
21 USC 351. (b) (1) Clause (4) of section 501(a) of such Act (relating to drugs deemed adulterated by reason of uncertified coal tar color) is amended to read as follows: “(4) if (A) it is a drug which bears or contains for purposes of coloring only, a color additive which is unsafe within the meaning of section 706(a), or (B) it is a color additive the intended use of which in or on drugs is for purposes of coloring only and is unsafe within the meaning of section 706(a).”

52 Stat. 1050.
21 USC 352. (2) Section 502 of such Act (relating to the circumstances under which drugs are deemed misbranded) is amended by adding at the end thereof the following new paragraph:

“(m) If it is a color additive the intended use of which in or on drugs is for the purpose of coloring only, unless its packaging and labeling are in conformity with such packaging and labeling requirements applicable to such color additive, as may be contained in regulations issued under section 706.”

Cosmetics

52 Stat. 1054.
21 USC 361. (c) (1) Section 601(e) of such Act (relating to cosmetics, other than hair dyes, deemed adulterated by reason of uncertified coal tar color) is amended to read as follows:

21 USC 376.
21 USC 362. “(e) If it is not a hair dye and it is, or it bears or contains, a color additive which is unsafe within the meaning of section 706(a).”

(2) Section 602 of such Act (relating to the circumstances under which cosmetics shall be deemed to be misbranded) is amended by adding at the end thereof the following new paragraph:

“(e) If it is a color additive, unless its packaging and labeling are in conformity with such packaging and labeling requirements, applicable to such color additive, as may be contained in regulations issued under section 706. This paragraph shall not apply to packages of color additives which, with respect to their use for cosmetics, are marketed and intended for use only in or on hair dyes (as defined in the last sentence of section 601(a)).”

REGULATIONS TO ASSURE SAFETY OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

SEC. 103. (a) Such Act is further amended by—

- 21 USC 346. (1) repealing subsection (b) of section 406 and striking out the subsection designation “(a)” after “SEC. 406.” in such section;
21 USC 354. (2) repealing section 504;
21 USC 364. (3) repealing section 604; and
21 USC 371. (4) amending section 701(e) by (A) striking out “406 (a) or

(b)" and inserting in lieu thereof "406"; (B) striking out "504, or 604,"; and (C) inserting the word "or" after "501(b)."

(b) Section 706 of such Act is amended to read as follows:

52 Stat. 1058.
21 USC 376.

"LISTING AND CERTIFICATION OF COLOR ADDITIVES FOR FOODS, DRUGS, AND COSMETICS

"When Color Additives Deemed Unsafe

"SEC. 706. (a) A color additive shall, with respect to any particular use (for which it is being used or intended to be used or is represented as suitable) in or on food or drugs or cosmetics, be deemed unsafe for the purposes of the application of section 402(c), section 501(a) (4), or section 601(e), as the case may be, unless—

52 Stat. 1047,
1049, 1054.

"(1) (A) there is in effect, and such additive and such use are in conformity with, a regulation issued under subsection (b) of this section listing such additive for such use, including any provision of such regulation prescribing the conditions under which such additive may be safely used, and (B) such additive either (i) is from a batch certified, in accordance with regulations issued pursuant to subsection (c), for such use, or (ii) has, with respect to such use, been exempted by the Secretary from the requirement of certification; or

21 USC 342,
351, 361.

"(2) such additive and such use thereof conform to the terms of an exemption which is in effect pursuant to subsection (f) of this section.

While there are in effect regulations under subsections (b) and (c) of this section relating to a color additive or an exemption pursuant to subsection (f) with respect to such additive, an article shall not, by reason of bearing or containing such additive in all respects in accordance with such regulations or such exemption, be considered adulterated within the meaning of clause (1) of section 402(a) if such article is a food, or within the meaning of section 601(a) if such article is a cosmetic other than a hair dye (as defined in the last sentence of section 601(a)).

21 USC 342,
361.

"Listing of Colors

"(b) (1) The Secretary shall, by regulation, provide for separately listing color additives for use in or on food, color additives for use in or on drugs, and color additives for use in or on cosmetics, if and to the extent that such additives are suitable and safe for any such use when employed in accordance with such regulations.

"(2) (A) Such regulations may list any color additive for use generally in or on food, or in or on drugs, or in or on cosmetics, if the Secretary finds that such additive is suitable and may safely be employed for such general use.

"(B) If the data before the Secretary do not establish that the additive satisfies the requirements for listing such additive on the applicable list pursuant to subparagraph (A) of this paragraph, or if the proposal is for listing such additive for a more limited use or uses, such regulations may list such additive only for any more limited use or uses for which it is suitable and may safely be employed.

"(3) Such regulations shall, to the extent deemed necessary by the Secretary to assure the safety of the use or uses for which a particular color additive is listed, prescribe the conditions under which such additive may be safely employed for such use or uses (including, but not limited to, specifications, hereafter in this section referred to as tolerance limitations, as to the maximum quantity or quantities which may be used or permitted to remain in or on the article or articles in or on which it is used; specifications as to the manner in which such additive

may be added to or used in or on such article or articles; and directions or other labeling or packaging requirements for such additive).

"(4) The Secretary shall not list a color additive under this section for a proposed use unless the data before him establish that such use, under the conditions of use specified in the regulations, will be safe: *Provided, however,* That a color additive shall be deemed to be suitable and safe for the purpose of listing under this subsection for use generally in or on food, while there is in effect a published finding of the Secretary declaring such substance exempt from the term 'food additive' because of its being generally recognized by qualified experts as safe for its intended use, as provided in section 201(s).

¹21 USC 321.

"(5) (A) In determining, for the purposes of this section, whether a proposed use of a color additive is safe, the Secretary shall consider, among other relevant factors—

"(i) the probable consumption of, or other relevant exposure from, the additive and of any substance formed in or on food, drugs, or cosmetics because of the use of the additive;

"(ii) the cumulative effect, if any, of such additive in the diet of man or animals, taking into account the same or any chemically or pharmacologically related substance or substances in such diet;

"(iii) safety factors which, in the opinion of experts qualified by scientific training and experience to evaluate the safety of color additives for the use or uses for which the additive is proposed to be listed, are generally recognized as appropriate for the use of animal experimentation data; and

"(iv) the availability of any needed practicable methods of analysis for determining the identity and quantity of (I) the pure dye and all intermediates and other impurities contained in such color additive, (II) such additive in or on any article of food, drug, or cosmetic, and (III) any substance formed in or on such article because of the use of such additive.

"(B) A color additive (i) shall be deemed unsafe, and shall not be listed, for any use which will or may result in ingestion of all or part of such additive, if the additive is found by the Secretary to induce cancer when ingested by man or animal, or if it is found by the Secretary, after tests which are appropriate for the evaluation of the safety of additives for use in food, to induce cancer in man or animal, and (ii) shall be deemed unsafe, and shall not be listed, for any use which will not result in ingestion of any part of such additive, if, after tests which are appropriate for the evaluation of the safety of additives for such use, or after other relevant exposure of man or animal to such additive, it is found by the Secretary to induce cancer in man or animal.

"(C) (i) In any proceeding for the issuance, amendment, or repeal of a regulation listing a color additive, whether commenced by a proposal of the Secretary on his own initiative or by a proposal contained in a petition, the petitioner, or any other person who will be adversely affected by such proposal or by the Secretary's order issued in accordance with paragraph (1) of section 701(e) if placed in effect, may request, within the time specified in this subparagraph, that the petition or order thereon, or the Secretary's proposal, be referred to an advisory committee for a report and recommendations with respect to any matter arising under subparagraph (B) of this paragraph, which is involved in such proposal or order and which requires the exercise of scientific judgment. Upon such request, or if the Secretary within such time deems such a referral necessary, the Secretary shall forthwith appoint an advisory committee under subparagraph (D) of this paragraph and shall refer to it, together with all the data before him, such matter arising under subparagraph (B) for study thereof

21 USC 371.

and for a report and recommendations on such matter. A person who has filed a petition or who has requested the referral of a matter to an advisory committee pursuant to this subparagraph (C), as well as representatives of the Department of Health, Education, and Welfare, shall have the right to consult with such advisory committee in connection with the matter referred to it. The request for referral under this subparagraph, or the Secretary's referral on his own initiative, may be made at any time before, or within thirty days after, publication of an order of the Secretary acting upon the petition or proposal.

"(ii) Within sixty days after the date of such referral, or within an additional thirty days if the committee deems such additional time necessary, the committee shall, after independent study of the data furnished to it by the Secretary and other data before it, certify to the Secretary a report and recommendations, together with all underlying data and a statement of the reasons or basis for the recommendations. A copy of the foregoing shall be promptly supplied by the Secretary to any person who has filed a petition, or who has requested such referral to the advisory committee. Within thirty days after such certification, and after giving due consideration to all data then before him, including such report, recommendations, underlying data, and statement, and to any prior order issued by him in connection with such matter, the Secretary shall by order confirm or modify any order theretofore issued or, if no such prior order has been issued, shall by order act upon the petition or other proposal.

"(iii) Where—

"(I) by reason of subparagraph (B) of this paragraph, the Secretary has initiated a proposal to remove from listing a color additive previously listed pursuant to this section; and

"(II) a request has been made for referral of such proposal to an advisory committee;

the Secretary may not act by order on such proposal until the advisory committee has made a report and recommendations to him under clause (ii) of this subparagraph and he has considered such recommendations, unless the Secretary finds that emergency conditions exist necessitating the issuance of an order notwithstanding this clause.

"(D) The advisory committee referred to in subparagraph (C) of this paragraph shall be composed of experts selected by the National Academy of Sciences, qualified in the subject matter referred to the committee and of adequately diversified professional background, except that in the event of the inability or refusal of the National Academy of Sciences to act, the Secretary shall select the members of the committee. The size of the committee shall be determined by the Secretary. Members of an advisory committee shall receive as compensation for their services a reasonable per diem, which the Secretary shall by rules and regulations prescribe, for time actually spent in the work of the committee, and shall in addition be reimbursed for their necessary traveling and subsistence expenses while so serving away from their places of residence. The members shall not be subject to any other provisions of law regarding the appointment and compensation of employees of the United States. The Secretary shall furnish the committee with adequate clerical and other assistance, and shall by rules and regulations prescribe the procedure to be followed by the committee.

"(6) The Secretary shall not list a color additive under this subsection for a proposed use if the data before him show that such proposed use would promote deception of the consumer in violation of this Act or would otherwise result in misbranding or adulteration within the meaning of this Act.

"(7) If, in the judgment of the Secretary, a tolerance limitation is required in order to assure that a proposed use of a color additive will be safe, the Secretary—

"(A) shall not list the additive for such use if he finds that the data before him do not establish that such additive, if used within a safe tolerance limitation, would achieve the intended physical or other technical effect; and

"(B) shall not fix such tolerance limitation at a level higher than he finds to be reasonably required to accomplish the intended physical or other technical effect.

"(8) If, having regard to the aggregate quantity of color additive likely to be consumed in the diet or to be applied to the human body, the Secretary finds that the data before him fail to show that it would be safe and otherwise permissible to list a color additive (or pharmacologically related color additives) for all the uses proposed therefor and at the levels of concentration proposed, the Secretary shall, in determining for which use or uses such additive (or such related additives) shall be or remain listed, or how the aggregate allowable safe tolerance for such additive or additives shall be allocated by him among the uses under consideration, take into account, among other relevant factors (and subject to the paramount criterion of safety), (A) the relative marketability of the articles involved as affected by the proposed uses of the color additive (or of such related additives) in or on such articles, and the relative dependence of the industries concerned on such uses; (B) the relative aggregate amounts of such color additive which he estimates would be consumed in the diet or applied to the human body by reason of the various uses and levels of concentration proposed; and (C) the availability, if any, of other color additives suitable and safe for one or more of the uses proposed.

"Certification of Colors

"(c) The Secretary shall further, by regulation, provide (1) for the certification, with safe diluents or without diluents, of batches of color additives listed pursuant to subsection (b) and conforming to the requirements for such additives established by regulations under such subsection and this subsection, and (2) for exemption from the requirement of certification in the case of any such additive, or any listing or use thereof, for which he finds such requirement not to be necessary in the interest of the protection of the public health: *Provided*, That, with respect to any use in or on food for which a listed color additive is deemed to be safe by reason of the proviso to paragraph (4) of subsection (b), the requirement of certification shall be deemed not to be necessary in the interest of public health protection.

"Procedure for Issuance, Amendment, or Repeal of Regulations

52 Stat. 1055.
21 USC 371.

"(d) The provisions of section 701 (e), (f), and (g) of this Act shall, subject to the provisions of subparagraph (C) of subsection (b) (5) of this section, apply to and in all respects govern proceedings for the issuance, amendment, or repeal of regulations under subsection (b) or (c) of this section (including judicial review of the Secretary's action in such proceedings) and the admissibility of transcripts of the record of such proceedings in other proceedings, except that—

"(1) if the proceeding is commenced by the filing of a petition, notice of the proposal made by the petition shall be published in general terms by the Secretary within thirty days after such filing, and the Secretary's order (required by paragraph (1) of section 701(e)) acting upon such proposal shall, in the absence of prior

referral (or request for referral) to an advisory committee, be issued within ninety days after the date of such filing, except that the Secretary may (prior to such ninetieth day), by written notice to the petitioner, extend such ninety-day period to such time (not more than one hundred and eighty days after the date of filing of the petition) as the Secretary deems necessary to enable him to study and investigate the petition;

“(2) any report, recommendations, underlying data, and reasons certified to the Secretary by an advisory committee appointed pursuant to subparagraph (D) of subsection (b) (5) of this section, shall be made a part of the record of any hearing if relevant and material, subject to the provisions of section 7(c) of the Administrative Procedure Act (5 U.S.C., sec. 1006(c)). The advisory committee shall designate a member to appear and testify at any such hearing with respect to the report and recommendations of such committee upon request of the Secretary, the petitioner, or the officer conducting the hearing, but this shall not preclude any other member of the advisory committee from appearing and testifying at such hearing; 60 Stat. 241.

“(3) the Secretary's order after public hearing (acting upon objections filed to an order made prior to hearing) shall be subject to the requirements of section 409(f) (2); and 72 Stat. 1787.
21 USC 348.

“(4) the scope of judicial review of such order shall be in accordance with the fourth sentence of paragraph (2), and with the provisions of paragraph (3), of section 409(g). 72 Stat. 1788.
21 USC 348.

“Fees

“(e) The admitting to listing and certification of color additives, in accordance with regulations prescribed under this Act, shall be performed only upon payment of such fees, which shall be specified in such regulations, as may be necessary to provide, maintain, and equip an adequate service for such purposes.

“Exemptions

“(f) The Secretary shall by regulations (issued without regard to subsection (d)) provide for exempting from the requirements of this section any color additive or any specific type of use thereof, and any article of food, drug, or cosmetic bearing or containing such additive, intended solely for investigational use by qualified experts when in his opinion such exemption is consistent with the public health.”

CONFIDENTIALITY OF TRADE SECRETS

SEC. 104. Section 301(j), as amended, of such Act, prohibiting disclosure of trade secrets, is amended by striking out “or 704” and inserting in lieu thereof “704, or 706”. 52 Stat. 1042.
21 USC 331.

CHANGES IN CROSS-REFERENCES AND TERMINOLOGY

SEC. 105. Such Act is further amended by—

(a) striking out, in section 301(i) thereof (relating to forgery or unauthorized use of certain identification devices), “404, 406 52 Stat. 1042.
21 USC 331.

(b), 504, 506, 507, or 604”, and inserting in lieu thereof “404, 506, 507, or 706”;

(b) (1) striking out, in clause (3) of section 303(c) (relating to color manufacturer's guarantee), the word “coal-tar” wherever it appears in such clause, and (2) inserting after the word 52 Stat. 1043.
21 USC 333.

52 Stat. 1047.
21 USC 342.

“color”, wherever it appears in such clause, the word “additive”; and

(c) striking out “harmless coloring” in section 402(d) (relating to nonnutritive substances in confectionery) and inserting in lieu thereof “authorized coloring”.

TITLE II—EFFECTIVE DATE, TRANSITIONAL PROVISIONS, AND EFFECT ON OTHER LAWS

DEFINITIONS

SEC. 201. As used in this title, the term “basic Act” means the Federal Food, Drug, and Cosmetic Act; the term “enactment date” means the date of enactment of this Act; and other terms, insofar as also used in the basic Act (whether before or after enactment of this Act) shall have the same meaning as they have, or had when in effect, under the basic Act.

EFFECTIVE DATE

SEC. 202. This Act shall, subject to the provisions of section 203, take effect on the enactment date.

PROVISIONAL LISTINGS OF COMMERCIALY ESTABLISHED COLORS

52 Stat. 1058.
21 USC 376.

SEC. 203. (a) (1) The purpose of this section is to make possible, on an interim basis for a reasonable period, through provisional listings, the use of commercially established color additives to the extent consistent with the public health, pending the completion of the scientific investigations needed as a basis for making determinations as to listing of such additives under the basic Act as amended by this Act. A provisional listing (including a deemed provisional listing) of a color additive under this section for any use shall, unless sooner terminated or expiring under the provisions of this section, expire (A) on the closing date (as defined in paragraph (2) of this subsection) or (B) on the effective date of a listing of such additive for such use under section 706 of the basic Act, whichever date first occurs.

(2) For the purposes of this section, the term “closing date” means (A) the last day of the two and one-half year period beginning on the enactment date or (B), with respect to a particular provisional listing (or deemed provisional listing) of a color additive or use thereof, such later closing date as the Secretary may from time to time establish pursuant to the authority of this paragraph. The Secretary may by regulation, upon application of an interested person or on his own initiative, from time to time postpone the original closing date with respect to a provisional listing (or deemed provisional listing) under this section of a specified color additive, or of a specified use or uses of such additive, for such period or periods as he finds necessary to carry out the purpose of this section, if in the Secretary’s judgment such action is consistent with the objective of carrying to completion in good faith, as soon as reasonably practicable, the scientific investigations necessary for making a determination as to listing such additive, or such specified use or uses thereof, under section 706 of the basic Act. The Secretary may terminate a postponement of the closing date at any time if he finds that such postponement should not have been granted, or that by reason of a change in circumstances the basis for such postponement no longer exists, or that there has been a failure to comply with a requirement for submission of progress reports or with other conditions attached to such postponement.

(b) Subject to the other provisions of this section—

(1) any color additive which, on the day preceding the enactment date, was listed and certifiable for any use or uses under section 406(b), 504, or 604, or under the third proviso of section 402(c), of the basic Act, and of which a batch or batches had been certified for such use or uses prior to the enactment date, and

52 Stat. 1049,
1052, 1055,
1047.

(2) any color additive which was commercially used or sold prior to the enactment date for any use or uses in or on any food, drug, or cosmetic, and which either, (A), on the day preceding the enactment date, was not a material within the purview of any of the provisions of the basic Act enumerated in paragraph (1) of this subsection, or (B) is the color additive known as synthetic beta-carotene,

21 USC 346,
354, 364,
342.

shall, beginning on the enactment date, be deemed to be provisionally listed under this section as a color additive for such use or uses.

(c) Upon request of any person, the Secretary, by regulations issued under subsection (d), shall without delay, if on the basis of the data before him he deems such action consistent with the protection of the public health, provisionally list a material as a color additive for any use for which it was listed, and for which a batch or batches of such material had been certified, under section 406(b), 504, or 604 of the basic Act prior to the enactment date, although such color was no longer listed and certifiable for such use under such sections on the day preceding the enactment date. Such provisional listing shall take effect on the date of publication.

(d) (1) The Secretary shall, by regulations issued or amended from time to time under this section—

(A) insofar as practicable promulgate and keep current a list or lists of the color additives, and of the particular uses thereof, which he finds are deemed provisionally listed under subsection (b), and the presence of a color additive on such a list with respect to a particular use shall, in any proceeding under the basic Act, be conclusive evidence that such provisional listing is in effect;

(B) provide for the provisional listing of the color additives and particular uses thereof specified in subsection (c);

(C) provide, with respect to particular uses for which color additives are or are deemed to be provisionally listed, such temporary tolerance limitations (including such limitations at zero level) and other conditions of use and labeling or packaging requirements, if any, as in his judgment are necessary to protect the public health pending listing under section 706 of the basic Act;

52 Stat. 1058.
21 USC 376.

(D) provide for the certification of batches of such color additives (with or without diluents) for the uses for which they are so listed or deemed to be listed under this section, except that such an additive which is a color additive deemed provisionally listed under subsection (b) (2) of this section shall be deemed exempt from the requirement of such certification while not subject to a tolerance limitation; and

(E) provide for the termination of a provisional listing (or deemed provisional listing) of a color additive or particular use thereof forthwith whenever in his judgment such action is necessary to protect the public health.

(2) (A) Except as provided in subparagraph (C) of this paragraph, regulations under this section shall, from time to time, be issued, amended, or repealed by the Secretary without regard to the requirements of the basic Act, but for the purposes of the application of section 706(e) of the basic Act (relating to fees) and of determining the availability of appropriations of fees (and of advance deposits

to cover fees), proceedings, regulations, and certifications under this section shall be deemed to be proceedings, regulations, and certifications under such section 706. Regulations providing for fees (and advance deposits to cover fees), which on the day preceding the enactment date were in effect pursuant to section 706 of the basic Act, shall be deemed to be regulations under such section 706 as amended by this Act, and appropriations of fees (and advance deposits) available for the purposes specified in such section 706 as in effect prior to the enactment date shall be available for the purposes specified in such section 706 as so amended.

(B) If the Secretary, by regulation—

(i) has terminated a provisional listing (or deemed provisional listing) of a color additive or particular use thereof pursuant to paragraph (1) (E) of this subsection; or

(ii) has, pursuant to paragraph (1) (C) or paragraph (3) of this subsection, initially established or rendered more restrictive a tolerance limitation or other restriction or requirement with respect to a provisional listing (or deemed provisional listing) which listing had become effective prior to such action,

any person adversely affected by such action may, prior to the expiration of the period specified in clause (A) of subsection (a) (2) of this section, file with the Secretary a petition for amendment of such regulation so as to revoke or modify such action of the Secretary, but the filing of such petition shall not operate to stay or suspend the effectiveness of such action. Such petition shall, in accordance with regulations, set forth the proposed amendment and shall contain data (or refer to data which are before the Secretary or of which he will take official notice), which show that the revocation or modification proposed is consistent with the protection of the public health. The Secretary shall, after publishing such proposal and affording all interested persons an opportunity to present their views thereon orally or in writing, act upon such proposal by published order.

(C) Any person adversely affected by an order entered under subparagraph (B) of this paragraph may, within thirty days after its publication, file objections thereto with the Secretary, specifying with particularity the provisions of the order deemed objectionable, stating reasonable grounds for such objections, and requesting a public hearing upon such objections. The Secretary shall hold a public hearing on such objections and shall, on the basis of the evidence adduced at such hearing, act on such objections by published order. Such order may reinstate a terminated provisional listing, or increase or dispense with a previously established temporary tolerance limitation, or make less restrictive any other limitation established by him under paragraph (1) or (3) of this subsection, only if in his judgment the evidence so adduced shows that such action will be consistent with the protection of the public health. An order entered under this subparagraph shall be subject to judicial review in accordance with section 701(f) of the basic Act except that the findings and order of the Secretary shall be sustained only if based upon a fair evaluation of the entire record at such hearing. No stay or suspension of such order shall be ordered by the court pending conclusion of such judicial review.

(D) On and after the enactment date, regulations, provisional listings, and certifications (or exemptions from certification) in effect under this section shall, for the purpose of determining whether an article is adulterated or misbranded within the meaning of the basic Act by reason of its being, bearing, or containing a color additive, have the same effect as would regulations, listings, and certifications (or exemptions from certification) under section 706 of the basic Act.

A regulation, provisional listing or termination thereof, tolerance limitation, or certification or exemption therefrom, under this section shall not be the basis for any presumption or inference in any proceeding under section 706 (b) or (c) of the basic Act.

(3) For the purpose of enabling the Secretary to carry out his functions under paragraphs (1) (A) and (C) of this subsection with respect to color additives deemed provisionally listed, he shall, as soon as practicable after enactment of this Act, afford by public notice a reasonable opportunity to interested persons to submit data relevant thereto. If the data so submitted or otherwise before him do not, in his judgment, establish a reliable basis for including such a color additive or particular use or uses thereof in a list or lists promulgated under paragraph (1) (A), or for determining the prevailing level or levels of use thereof prior to the enactment date with a view to prescribing a temporary tolerance or tolerances for such use or uses under paragraph (1) (C), the Secretary shall establish a temporary tolerance limitation at zero level for such use or uses until such time as he finds that it would not be inconsistent with the protection of the public health to increase or dispense with such temporary tolerance limitation.

EFFECT ON MEAT INSPECTION AND POULTRY PRODUCTS INSPECTION ACTS

SEC. 204. Nothing in this Act shall be construed to exempt any meat or meat food product, poultry or poultry product, or any person from any requirement imposed by or pursuant to the Meat Inspection Act of March 4, 1907, 34 Stat. 1260, as amended or extended (21 U.S.C. 71 and the following), or the Poultry Products Inspection Act (21 71 Stat. 441. U.S.C. 451 and the following).

Approved July 12, 1960.

